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Attorneys for Defendants
INNOVATIVE BIODEFENSE, INC., COLETTE
COZEAN, & HOTAN BAROUGH

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

INNOVATIVE BIODEFENSE, INC. ET
AL.,

Defendants.

Case No: 8:18-cv-00996-DOC-JDE

**DECLARATION OF KIRBY D.
BEHRE IN SUPPORT OF
INNOVATIVE BIODEFENSE, INC.,
ET AL. OPPOSITION TO
PLAINTIFF'S MOTION FOR
SUMMARY JUDGMENT**

Judge: Hon. David O. Carter
Pretrial Conference: Nov. 18, 2019
Trial Date: Dec. 17, 2019

1 I, KIRBY D. BEHRE, declare as follows:

2 1. I am an attorney admitted *pro hac vice* before this Court. I am a member
3 at Miller & Chevalier Chartered, attorneys of record for Defendants Innovative
4 BioDefense, Inc. (“IBD”), Colette Cozean, and Hotan Barough. I have personal
5 knowledge of the facts set forth herein. If called as a witness, I could and would
6 competently testify to the matters stated herein. I make this declaration in support of
7 Defendants IBD’s, Colette Cozean’s, and Hotan Barough’s Opposition to the
8 Plaintiff’s Motion for Summary Judgment.

9 2. On September 5, 2019, Dr. Colette Cozean was deposed by attorneys for
10 the Plaintiff. A true and correct copy of excerpts of the deposition transcript is attached
11 as **Exhibit 1**.

12 3. On August 15, 2019, Hotan Barough was deposed by attorneys for the
13 Plaintiff. A true and correct copy of excerpts of the deposition transcript is attached as
14 **Exhibit 2**.

15 4. On August 30, 2019, Plaintiff presented a chart of website statements
16 during the Rule 30(b)(6) deposition of the FDA, which was marked as Exhibit 2.
17 30(b)(6) Dep. Ex. 2. A true and correct copy of the 30(b)(2) Deposition Exhibit 2 is
18 attached as **Exhibit 3**.

19 5. On November 7, 2013, Mr. Paul Hyman sent a letter to Howard
20 Sklamberg, Esq. A true and correct copy of the letter is attached as **Exhibit 4**.

21 6. On September 16, 2019, Plaintiff served its Responses to Defendants’
22 First Set of Request for Admission of Facts. A true and correct copy of the Responses
23 is attached as **Exhibit 5**

24 7. On June 30, 2015, a Warning Letter was issued by the FDA and FTC to
25 Dr. Cozean and was marked as Exhibit 9 during the 30(b)(6) deposition of the FDA.
26 30(b)(6) Dep. Ex. 9. A true and correct copy of the 30(b)(2) Deposition Exhibit 9 is
27 attached as **Exhibit 6**.

1 8. On April 18, 2014, an email was sent from Anuj Shah to Heath Harley
2 and Sudha Shukla which is marked as Shah Exhibit 1. Shah Dep. Ex. 1. A true and
3 correct copy of Shah Deposition Exhibit 1 is attached as **Exhibit 7**.

4 9. On December 12, 2014, USAID issued a press release, “United States
5 Announces Results of Grand Challenge to Fight Ebola,” which was marked as Exhibit
6 15. 30(b)(6) Dep. Ex. 15. A true and correct copy of the 30(b)(6) Deposition Exhibit
7 15 is attached as **Exhibit 8**.

8 10. On March 19, 2015, an email was sent between FDA employees and
9 USAID employees. A true and correct copy of the produced document GOV-
10 00005339 is attached as **Exhibit 9**.

11 11. On December 23, 2014, Mr. Paul Hyman sent a letter to Cynthia A.
12 Schnedar, Director, Office of Compliance, FDA. This was marked as Exhibit 4. Shukla
13 Dep. Ex. 4. A true and correct copy of Shukla Deposition Exhibit 4 is attached as
14 **Exhibit 10**.

15 12. On December 24, 2014, an email was sent by Anuj Shah to FDA
16 employees discussing Mr. Hyman’s letter of December 23, 2014, which is marked as
17 Exhibit 4. Shah Dep. Ex. 4. A true and correct copy of the Shah Deposition Exhibit 4
18 is attached as **Exhibit 11**.

19 13. On April 20, 2015, a letter was sent from USAID to Aquarius Global
20 Energy Partners, LLC rescinding the Award for Zylast products, which is marked as
21 J. Cozean Dep. Ex. 19. J. Cozean Dep. Ex. 19. A true and correct copy of the J. Cozean
22 Deposition Exhibit 19 is attached as **Exhibit 12**.

23 14. On November 30, 2015, an email was sent from Heath Harley to Tina
24 Smith stating they contacted USAID. A true and correct copy of the produced
25 document GOV-00002318 is attached as **Exhibit 13**.

26 15. On October 9, 2019, Dr. Raymond Brullo was deposed by attorneys for
27 the Defendant. A true and correct copy of excerpts of the deposition transcript is
28 attached as **Exhibit 14**.

1
2 16. On October 1, 2015, an email was sent from Paul Hyman to Raymond
3 Brullo and others, which was marked as Exhibit 9. Smith Dep. Ex. 9. A true and correct
4 copy of the Smith Deposition Exhibit 9 is attached as **Exhibit 15**.

5 17. On February 20, 2015, Tina Smith sent an email to Heath Harley
6 regarding a voice mail message from Paul Hyman, which was marked as Exhibit 4.
7 Smith Dep. Ex. 4. A true and correct copy of the Smith Deposition Exhibit 4 is attached
8 as **Exhibit 16**.

9 18. On February 19, 2015, Paul Hyman left a voicemail message with Sudha
10 Shukla at the FDA. A true and correct copy of the audio recording has been lodged as
11 **Exhibit 17**.

12 19. On March 13, 2015, Paul Hyman sent an email to Sudha Shukla, which
13 was marked as Exhibit 5. Smith Dep. Ex. 5. A true and correct copy of the Smith
14 Deposition Exhibit 5 is attached as **Exhibit 18**.

15 20. On April 1, 2015, Paul Hyman sent a letter to Sudha Shukla, Project
16 Management Officer, FDA. A true and correct copy of the letter is attached as **Exhibit**
17 **19**.

18 21. On April 1, 2015, Paul Hyman emailed Cynthia Schnedar regarding
19 Zylast products. A true and correct copy the email is attached as **Exhibit 20**.

20 22. On April 10, 2015, Paul Hyman sent an email to Elizabeth Miller
21 regarding Zylast products. A true and correct copy of the email is attached as **Exhibit**
22 **21**.

23 23. On April 10, 2015, Paul Hyman left a voicemail for Elizabeth Miller. A
24 true and correct copy of the audio recording has been lodged as **Exhibit 22**.

25 24. On April 15, 2015, Sudha Shukla sent an email to FDA employees
26 regarding a voicemail message from Paul Hyman. A true and correct copy of the email
27 is attached as **Exhibit 23**.

1 25. On April 15, 2015, Paul Hyman left a voicemail message for Sudha
2 Shukla. A true and correct copy of the audio recording has been lodged as **Exhibit 24.**

3 26. On April 16, 2015, Elizabeth Miller emailed Sudha Shukla regarding a
4 call she had with Paul Hyman, which was marked as Exhibit 7. Smith Dep. Ex. 7. A
5 true and correct copy of the Smith Deposition Exhibit 7 is attached as **Exhibit 25.**

6 27. On May 13, 2015, Paul Hyman sent an email to Sudha Shukla. A true and
7 correct copy of the email is attached as **Exhibit 26.**

8 28. On May 13, 2015, Paul Hyman sent a letter to Sudha Shukla. A true and
9 correct copy of the letter is attached as **Exhibit 27.**

10 29. On August 5, 2015, Paul Hyman sent an email to Sudha Shukla regarding
11 Zylast products. A true and correct copy of the email is attached as **Exhibit 28.**

12 30. On August 6, 2015, Paul Hyman sent an email to Cynthia Schnedar
13 following up on an email sent to Sudha Shukla. A true and correct copy of email is
14 attached as **Exhibit 29.**

15 31. A website printout from the Centers for Disease Control and Prevention
16 regarding “Hand Hygiene in Non-U.S. General Healthcare Settings” was marked as
17 Shah Exhibit 15. Shah. Dep. Ex. 15. A true and correct copy of the Shah Deposition
18 Exhibit 15 is attached as **Exhibit 30.**

19 32. A website printout from the Centers for Disease Control and Prevention
20 regarding “Handwashing,” was marked as Shah Exhibit 16. Shah. Dep. Ex. 16. A true
21 and correct copy of the Shah Deposition Exhibit 16 is attached as **Exhibit 31.**

22 33. A website printout from U.S. Department of Education “Guidance for
23 Schools and Districts About Ebola,” was marked as Exhibit 26. C. Cozean Dep. Ex.
24 26. A true and correct copy of the C. Cozean Deposition Exhibit 26 is attached as
25 **Exhibit 32.**

26 34. A website printout from National Center for Complementary and
27 Integrative Health was produced as document IBD_0011002. A true and correct copy
28 of the document is attached as **Exhibit 33.**

1 35. On October 15, 2019, Dr. David Dyer prepared a Declaration. A true and
2 correct copy of the Dr. David Dyer Declaration is attached as **Exhibit 34**.

3 36. On August 30, 2019, the FDA Rule 30(b)(6) designee, Commander Tina
4 Smith, was deposed by attorneys for the Defendant. A true and correct copy of excerpts
5 of the deposition transcript is attached as **Exhibit 35**.

6 37. On August 20, 2019, Anuj Shah was deposed by attorneys for the
7 Defendant. A true and correct copy of excerpts of the deposition transcript is attached
8 as **Exhibit 36**.

9 38. On July 19, 2019, Elizabeth Miller was deposed by attorneys for the
10 Defendant. A true and correct copy of excerpts of the deposition transcript is attached
11 as **Exhibit 37**.

12 39. On June 20, 2019, Heath Harley was deposed by attorneys for the
13 Defendant. A true and correct copy of excerpts of the deposition transcript is attached
14 as **Exhibit 38**.

15 40. On May 10, 2019, Sudha Shukla was deposed by attorneys for the
16 Defendant. A true and correct copy of excerpts of the deposition transcript is attached
17 as **Exhibit 39**.

18 41. On May 30, 2019, Commander Tina Walther Smith was deposed by
19 attorneys for the Defendant. A true and correct copy of excerpts of the deposition
20 transcript is attached as **Exhibit 40**.

21 42. On October 8, 2019, Paul Hyman was deposed by attorneys for the
22 Defendant. A true and correct copy of excerpts of the deposition transcript is attached
23 as **Exhibit 41**.

24 43. On July 6, 2015, Raymond Brullo sent an email to Daniel Solis, Daniel
25 Cline, and Steven Porter, which was marked as Brullo Exhibit 1. Brullo Dep. Ex. 1. A
26 true and correct copy of the Brullo Deposition Exhibit 1 is attached as **Exhibit 42**.

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4 45. Websites from competitors make similar claims to Defendants. A true and
5 correct copy of the websites is attached as **Exhibit 44**.

6 46. On September 9, 2019, Jesse Cozean was deposed by attorneys for the
7 Plaintiff. A true and correct copy of excerpts of the deposition transcript is attached as
8 **Exhibit 45.**

9 47. On March 31, 2015, the FDA held a teleconference with IBD. A true and
10 correct copy of the minutes is attached as **Exhibit 46**.

12 I declare under penalty of perjury under the laws of the United States of America
13 that the foregoing is true and correct.

15 Executed on this 15th day of October, 2019, at Washington, D.C.

17 /s/ Kirby D. Behre
KIRBY D. BEHRE

INDEX OF EXHIBITS

EXHIBIT	DESCRIPTION
1	Excerpts of Colette Cozean Deposition Transcript (Sept. 5, 201)
2	Excerpts of Hotan Barough Deposition Transcript (Aug. 15, 2019)
3	FDA Rule 30(b)(6) Dep. Ex. 2
4	Nov. 7, 2013 Hyman Letter to Howard Sklamberg
5	Plaintiff's Responses to Defendants' Requests for Admission of Fact
6	June 30, 2015 Warning Letter
7	April 18, 2014 Email with Anuj Shah, Heath Harley and Sudha Shukla
8	December 12, 2014 USAID Press Release
9	March 19, 2015 Email with Tina Smith and Karen Winestock (GOV-00005339)
10	December 23, 2014 Hyman Letter to Cynthia Schnedar at FDA
11	December 24, 2012 Email from Anuj Shah to FDA employees
12	April 20, 2015 USAID Letter
13	November 30, 2015 Email from Heath Harley to Tina Smith (GOV-00002318)
14	Excerpts of Raymond Brullo Deposition Transcript (Oct. 9, 2019)

1		
2	15	October 1, 2015 Email from Paul Hyman to Raymond Brullo
3		
4	16	February 20, 2015 Email from Tina Smith to Heath Harley
5		
6	17	Voicemail from Paul Hyman to Sudha Shukla (GOV-00005756)
7		
8	18	March 13, 2015 Email from Paul Hyman to Sudha Shukla
9		
10	19	April 1, 2015 Letter from Paul Hyman to Shukla
11		
12	20	April 1, 2015 Email from Paul Hyman to Cynthia Schnedar
13		
14	21	April 10, 2015 Email from Paul Hyman to Elizabeth Miller (GOV-00012866)
15		
16	22	Voicemail from Paul Hyman to Elizabeth Miller (GOV-00012871)
17		
18	23	April 15, 2015 Email from Sudha Shukla forwarding Voicemail from Paul Hyman
19		
20	24	Voicemail from Paul Hyman to Sudha Shukla (GOV-00003242)
21		
22	25	April 16, 2015 Email from Elizabeth Miller to Sudha Shukla and others regarding call with Paul Hyman
23		
24	26	May 13, 2015 Email from Paul Hyman to Sudha Shukla
25		
26	27	May 13, 2015 Letter from Paul Hyman to Sudha Shukla
27		
28	28	August 5, 2015 Email from Paul Hyman to Sudha Shukla
	29	August 6, 2015 Email from Paul Hyman to Cynthia Schnedar
	30	CDC Website Printout Regarding "Hand Hygiene in Non-U.S. General Healthcare Settings"

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31	CDC Website Printout Regarding “Handwashing”
32	U.S. Department of Education Website Printout Regarding “Guidance for Schools and Districts About Ebola”
33	National Center for Complementary and Integrative Health Website Printout (IBD 00011002)
34	Declaration of David Dyer (Oct. 15, 2015)
35	Excerpts of Rule 30(b)(6) Deposition Transcript (Aug. 30, 2019)
36	Excerpts of Anuj Shah Deposition Transcript (Aug. 20, 2019)
37	Excerpts of Elizabeth Miller Deposition Transcript (July 19, 2019)
38	Excerpts of Heath Harley Deposition Transcript (June 20, 2019)
39	Excerpts of Sudha Shukla Deposition Transcript (May 10, 2019)
40	Excerpts of Tina Smith Deposition Transcript (May 30, 2019)
41	Excerpts of Paul Hyman Deposition Transcripts (Oct. 8, 2019)
42	July 6, 2015 Email from Raymond Brullo to Daniel Solis, Daniel Cline, and Steven Porter
43	April 8, 2015 Letter from Marc Sanchez to Tina (Walther) Smith
44	Competitor Website Printouts
45	Excerpts of Jesse Cozean Deposition Transcript (Sept. 9, 2019)
46	March 31, 2015 Internal Memorandum of Meeting Minutes

1 Dated: October 15, 2019

MILLER & CHEVALIER CHARTERED

2
3 By: /s/ Kirby D. Behre

KIRBY D. BEHRE

4 Attorneys for Defendants

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14
15 *Attorneys for Defendants*
16 *INNOVATIVE BIODEFENSE, INC., COLETTE COZEAN, AND HOTAN*
17 *BAROUGH*
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CERTIFICATE OF SERVICE

I hereby certify that on October 15, 2019, I electronically filed the foregoing with the Clerk of Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

Douglas Ross
US Department of Justice
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Washington, DC 20530
Email: douglas.ross2@usdoj.gov

Counsel for Plaintiff

/s/ Kirby D. Behre
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Attorneys for Defendants
**INNOVATIVE BIODEFENSE, INC.,
COLETTE COZEAN, AND HOTAN
BAROUGH**

EXHIBIT 1

1 UNITED STATES DISTRICT COURT
2 FOR THE CENTRAL DIVISION OF CALIFORNIA
3 SOUTHERN DIVISION
4

5 UNITED STATES OF AMERICA,)
6 Plaintiff,)
7 vs.) No. 8:18 CV 996-DOC
(JDE)
8 INNOVATIVE BIODEFENSE, INC.,)
et al.,)
9 Defendants.)
10 _____)
11
12
13
14

15 DEPOSITION OF COLETTE COZEAN, taken on behalf
16 of the Plaintiff, at 411 West 4th Street, Suite 8000,
17 Santa Ana, California, commencing at 9:32 A.M., on
18 Thursday, September 5, 2019, pursuant to Notice, before
19 CANDICE HESLINGTON, CSR No. 13741, a Certified Shorthand
20 Reporter, in and for the County of Los Angeles, State of
21 California.

22 ***
23
24
25

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<p>1 a leave-on.</p> <p>2 THE REPORTER: Thank you.</p> <p>3 THE WITNESS: It's a hyphenated word, and BZK</p> <p>4 was.</p> <p>5 BY MR. ROSS: 09:58:47AM</p> <p>6 Q. Which products are being produced with BZK?</p> <p>7 A. It's called a Lotion K -- Zylast Lotion K.</p> <p>8 Q. How is it being distributed?</p> <p>9 A. It would be --</p> <p>10 MR. BEHRE: Objection. Vague. Foundation. 09:59:14AM</p> <p>11 THE WITNESS: It is not yet being distributed,</p> <p>12 and it would be distributed through the same channels</p> <p>13 that all our other products are distributed.</p> <p>14 BY MR. ROSS:</p> <p>15 Q. Does IBD sell or cause to be distributed any 09:59:44AM</p> <p>16 other products besides Zylast?</p> <p>17 A. No.</p> <p>18 Q. How would you describe the size --</p> <p>19 A. Oh.</p> <p>20 Q. -- of -- I'm sorry. 10:00:13AM</p> <p>21 A. Let me correct that answer. We will private</p> <p>22 label products for other people, but they are the Zylast</p> <p>23 technology, so I just wanted to clarify my answer to</p> <p>24 you.</p> <p>25 Q. Okay. How would you describe the size of IBD? 10:00:25AM</p>	<p>1 Q. Do you have any information about why they've</p> <p>2 reduced their sales agents?</p> <p>3 A. I do not.</p> <p>4 Q. What do you estimate IBD's market share in</p> <p>5 hand sanitizers is today? 10:02:56AM</p> <p>6 A. Well, less than 1 percent.</p> <p>7 Q. What's the basis for that?</p> <p>8 A. I know the overall size of the market, and I</p> <p>9 know our sales.</p> <p>10 Q. What do you estimate is annual gross revenue 10:03:10AM</p> <p>11 from Zylast sales presently?</p> <p>12 A. Is this confidential? Because we've never</p> <p>13 sent sales numbers out to anybody.</p> <p>14 MR. BEHRE: We can ask that it be treated as</p> <p>15 confidential. 10:03:42AM</p> <p>16 THE WITNESS: Okay. I think this year will</p> <p>17 come in between 100- and 150,000.</p> <p>18 BY MR. ROSS:</p> <p>19 Q. Was there a time when it was higher than that?</p> <p>20 A. Yes. 10:03:55AM</p> <p>21 Q. When was that?</p> <p>22 A. Before the FDA filed litigation.</p> <p>23 Q. What would you estimate was the high point for</p> <p>24 these revenues?</p> <p>25 A. Probably about 400- to 500,000 dollars. 10:04:08AM</p>
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<p>1 A. Miniscule.</p> <p>2 Q. Because?</p> <p>3 MR. BEHRE: Objection. Vague. Ambiguous.</p> <p>4 THE WITNESS: It has no employees. The people</p> <p>5 that do consult, consult on a part-time basis. Um, it 10:00:50AM</p> <p>6 has no offices.</p> <p>7 It has no -- you know, none of the things you</p> <p>8 normally would expect, like accounting or all those</p> <p>9 things. Everything is done for it by outside people,</p> <p>10 and its sales are very small. 10:01:16AM</p> <p>11 BY MR. ROSS:</p> <p>12 Q. How many sales agents does IBD use?</p> <p>13 MR. BEHRE: Objection. Foundation.</p> <p>14 THE WITNESS: I would say that there's</p> <p>15 probably between 10 and 20 sales agent groups, and I 10:01:40AM</p> <p>16 have no idea of how many sales agents each group has.</p> <p>17 BY MR. ROSS:</p> <p>18 Q. So it could be as many as 600?</p> <p>19 A. At times I think it has been that many.</p> <p>20 Q. But today you think it's fewer than that? 10:02:05AM</p> <p>21 A. I do.</p> <p>22 Q. What basis do you have for that?</p> <p>23 A. I know of a couple of the groups that have</p> <p>24 significantly reduced their number of sales agents, and</p> <p>25 I don't know about the rest of them. 10:02:36AM</p>	<p>1 Q. Do you recall stating in your deposition in</p> <p>2 the GOJO litigation that in late October 2012 you took</p> <p>3 orders for about \$10 million worth of Zylast products in</p> <p>4 the first two weeks of January?</p> <p>5 A. Yes, and that was true. 10:04:43AM</p> <p>6 Q. And what factors explain the drop from that</p> <p>7 level to what you're estimating?</p> <p>8 A. Well, that was an order. That person never</p> <p>9 paid, and so we never shipped product to them.</p> <p>10 Q. Who was -- 10:05:00AM</p> <p>11 A. So --</p> <p>12 Q. Oh, I'm sorry to interrupt. I didn't mean to.</p> <p>13 A. It's okay.</p> <p>14 Q. Who was that person?</p> <p>15 A. They were called Ocean 5 -- Oceans 5. 10:05:07AM</p> <p>16 Q. So what was the biggest order ever?</p> <p>17 MR. BEHRE: Objection. Vague. Ambiguous.</p> <p>18 THE WITNESS: I'm -- I'm just guessing from</p> <p>19 what I remember of the company. I would think maybe</p> <p>20 between 50- to 100,000. 10:05:39AM</p> <p>21 BY MR. ROSS:</p> <p>22 Q. What company was that?</p> <p>23 A. I think that was to a company called Picketts,</p> <p>24 and -- and that might have been their total orders, not</p> <p>25 just one order. I don't know. 10:05:59AM</p>

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<p>1 A. Um, she was introduced to me by somebody at a 2 get-together as a medical writer, and she came over with 3 all of her journals that she wrote and edited for. 4 Q. When the Zylast Direct Web site had been 5 reworked with her input, did you review the final 10:58:46AM 6 version before it was put up? 7 MR. BEHRE: Object- -- objection. Asked and 8 answered before the break. 9 THE WITNESS: As I said, I did not do a full 10 review of it. 10:58:57AM 11 BY MR. ROSS: 12 Q. Did there come a time when you reviewed the 13 content of that Zylast Direct Web site? 14 A. No. As I said, if she asked me questions 15 about something she didn't understand when she was 10:59:15AM 16 working on it, I would answer those questions. 17 Q. But at a later time after she had completed 18 her work and the Web site was ready to be put up again, 19 did you have -- ever have occasion after that to review 20 the Web site? 10:59:33AM 21 A. I never did a full review of the Web site. 22 Q. Did Sheryl Perez ask you to review the Web 23 site in the final version? 24 A. Not that I know of. 25 Q. Did Bruce Bugbee ask you for review of the Web 10:59:49AM</p>	<p>1 warning letter? 2 A. No. I think it was after the litigation or as 3 we were talking before the -- I think it was as we were 4 talking before the litigation started, but it wasn't 5 right after the warning letter. 11:02:15AM 6 Q. So the warning letter was issued on June 30, 7 2015. Litigation was filed originally in June of 2018. 8 You're referring to that interim period 9 between -- 10 A. I'm referring -- 11:02:38AM 11 Q. -- June 2015 -- 12 A. I'm referring to the time frame when Kirby was 13 talking with the DOJ prior to the filing of the 14 litigation. I believe that's when I called him. 15 Q. Do you recall what Hotan Barough's response 11:02:52AM 16 was to your suggestion that he review the statements? 17 A. Yeah. He said, "If the FDA would like any 18 changes, I'd be glad to make them. I don't want the FDA 19 to get upset with me." 20 Q. Did he make changes? 11:03:14AM 21 A. He called me back about 24 hours later and 22 said he made all the changes. 23 Q. Were there subsequent occasions where you 24 asked Zylast Direct to consider changing its Web site? 25 A. I can't remember if my conversation with Hotan 11:03:36AM</p>
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<p>1 site? 2 A. I don't think so. 3 (Phone ringing.) 4 MR. BEHRE: Is that you? 5 THE WITNESS: Uh-huh. 11:00:07AM 6 MR. BEHRE: Is that you? 7 BY MR. ROSS: 8 Q. Did Jeremy Born introduce you to Hotan 9 Barough? 10 A. I think so. 11:00:38AM 11 Q. For what purpose did he introduce Hotan to 12 you? 13 A. It's been so long ago. I don't even remember 14 how it happened. 15 Q. When Hotan Barough took over the Zylast Direct 11:00:57AM 16 Web site in late 2013 or 2014, was there already a Web 17 site called ZylastDirect.com? 18 A. Yes. 19 Q. Did you ever ask Hotan Barough to modify that 20 Web site? 11:01:35AM 21 A. No -- oh, yes, I did. Um, in response to the 22 comments from the FDA, I called him up and said, "The 23 FDA has problems with these statements. You might want 24 to consider removing or changing them." 25 Q. By "FDA comments," are you referring to the 11:01:59AM</p>	<p>1 was in one call or two, but there was only one short 2 period of time where I had any of those conversations. 3 Q. So you did not ask that he make changes this 4 year to the Zylast Direct Web site? 5 A. I could have. As I said, I think there might 11:04:15AM 6 have been two calls that were the same -- essentially 7 the same warning. 8 Q. Did you e-mail Hotan Barough about changing 9 the Web site ever? 10 A. I did not. 11:04:36AM 11 Q. There was a time that IBD had a Facebook page; 12 is that correct? 13 A. That is correct. 14 Q. And that's no longer available; is that 15 correct too? 11:04:59AM 16 A. I believe that is correct. 17 Q. Have you ever reviewed the Facebook page? 18 A. I do not know how to use Facebook, so the 19 answer is no. 20 Q. So you're not familiar with Zylast XP -- to 11:05:11AM 21 get to the Facebook page Facebook.com, slash, Zylast XP? 22 MR. BEHRE: Objection. I don't even 23 understand the question. Vague. Ambiguous. 24 THE WITNESS: As I said to you, I know we have 25 a Facebook page. That's the total sum of my knowledge. 11:05:41AM</p>

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<p>1 Exhibit 22. It's a page from the CDC's Web site with a</p> <p>2 heading of "Ebola, Ebola Virus Disease" with a</p> <p>3 subheading of "Handwashing."</p> <p>4 Do you see that?</p> <p>5 A. I do. 03:17:00PM</p> <p>6 Q. And what, if anything, does the CDC say on</p> <p>7 this page regarding the use of alcohol-based hand</p> <p>8 sanitizers?</p> <p>9 A. It says that they can be used when the hands</p> <p>10 are not visibly dirty, if they're between 60 and 03:17:12PM</p> <p>11 95 percent ethanol and several other things, as proper</p> <p>12 hygiene to reduce the spread of Ebola. This spreads by</p> <p>13 direct contact with the body fluids of an infected</p> <p>14 person.</p> <p>15 Q. Well, in fact, it says -- and I quote: 03:17:32PM</p> <p>16 "Hand hygiene is the most</p> <p>17 effective way to prevent the spread</p> <p>18 of dangerous germs like Ebola virus,"</p> <p>19 period, closed quote.</p> <p>20 And then it says: 03:17:45PM</p> <p>21 "Proper hand hygiene methods are</p> <p>22 described below."</p> <p>23 And the very first bullet is:</p> <p>24 "Use alcohol-based hand sanitizer</p> <p>25 when hands are not visibly dirty," 03:17:55PM</p>	<p>1 hands are not visibly soiled. This</p> <p>2 is because of its ability to kill</p> <p>3 germs like Ebola. It is quick to</p> <p>4 apply to hands and air dry. It is</p> <p>5 gentler to the skin." 03:19:06PM</p> <p>6 Q. Okay. And in crafting your company's position</p> <p>7 regarding the use of your product, did you consider what</p> <p>8 the CDC said?</p> <p>9 A. Yes.</p> <p>10 Q. And as best you are aware, is the CDC part of 03:19:22PM</p> <p>11 the federal government?</p> <p>12 A. Yes.</p> <p>13 Q. Is the FDA part of the federal government?</p> <p>14 A. Yes.</p> <p>15 Q. And did you rely upon what the federal 03:19:32PM</p> <p>16 government said about the use of hand sanitizers to kill</p> <p>17 Ebola?</p> <p>18 A. Yes.</p> <p>19 Q. Showing you next what we'll mark as</p> <p>20 Exhibit 24, this is a chart prepared by the FDA's expert 03:19:43PM</p> <p>21 witness. It's 19 pages in length. It has no heading</p> <p>22 other than "Table 1."</p> <p>23 (Defendants' Exhibit 24 was marked</p> <p>24 for identification by the court</p> <p>25 reporter and is bound separately.) 03:20:15PM</p>
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<p>1 closed quote.</p> <p>2 Do you see that?</p> <p>3 A. I do.</p> <p>4 Q. I'd like to next show you what we'll mark as</p> <p>5 Exhibit 23. 03:18:12PM</p> <p>6 (Defendants' Exhibit 23 was marked</p> <p>7 for identification by the court</p> <p>8 reporter and is bound separately.)</p> <p>9 BY MR. BEHRE:</p> <p>10 Q. This, too, is a page from the CDC's Web site 03:18:17PM</p> <p>11 from last month. It's also -- it's got the same heading</p> <p>12 on it of "Ebola Virus" -- "Ebola," paren, "Ebola Virus</p> <p>13 Disease," closed paren, and this page is subtitled "Hand</p> <p>14 Hygiene in Non-U.S. General Health Care Settings."</p> <p>15 Do you see that? 03:18:38PM</p> <p>16 A. I do.</p> <p>17 Q. Have you seen this page before?</p> <p>18 A. Yes.</p> <p>19 Q. And does it contain any statements regarding</p> <p>20 the use of hand sanitizers in preventing the spread and, 03:18:45PM</p> <p>21 in fact, killing Ebola?</p> <p>22 A. It says:</p> <p>23 "Alcohol-based hand sanitizers is</p> <p>24 a preferred method of routine hand</p> <p>25 hygiene in health care settings when 03:18:55PM</p>	<p>1 MR. BEHRE: And apologies. It's got some</p> <p>2 handwriting. That was not done by the witness, but this</p> <p>3 is the only copy that we had of the exhibit, so you can</p> <p>4 ignore the "Ex 2" on the top, "51/53 removed or</p> <p>5 altered," or "18 in WL." 03:20:29PM</p> <p>6 BY MR. BEHRE:</p> <p>7 Q. Have you had a chance to look at this exhibit?</p> <p>8 A. Yes.</p> <p>9 Q. And what does this exhibit show with regard to</p> <p>10 your company's willingness to remove and alter 03:20:36PM</p> <p>11 statements that were raised by the FDA, not only before</p> <p>12 the warning letter, but in the warning letter and in the</p> <p>13 complaint?</p> <p>14 A. It shows that we removed or changed 95 percent</p> <p>15 of what they talked to us about. 03:20:53PM</p> <p>16 Q. And with regard to this more than</p> <p>17 four-year-old ordeal you have been through, have you</p> <p>18 been willing to modify what was said on your Web sites</p> <p>19 and in any other forum to resolve things with the FDA?</p> <p>20 A. Yes. 03:21:10PM</p> <p>21 Q. Do you remain willing to do that?</p> <p>22 A. Yes.</p> <p>23 Q. If the FDA sat here today and asked you to</p> <p>24 remove something, would you do it?</p> <p>25 A. Yes, as long as the FDA was treating us fairly 03:21:18PM</p>

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<p>1 with our competitors, because we can't be in a position 2 where we can't make statements and they make all the 3 same statements and be able to sell effectively. 4 Q. And by that statement, what do you mean? 5 What are your competitors doing that put you 03:21:33PM 6 at a competitive disadvantage? 7 A. All of our competitors are reporting on 8 certain viruses and bacteria. They're reporting on 9 reduced infections. They're reporting on reduced 10 illnesses. Everything the FDA is frustrated with us -- 03:21:48PM 11 or complains about us saying, our competitors are doing. 12 Q. Specifically with regard to GOJO, the makers 13 of Purell, the dominant player in the market -- 14 A. Yes. 15 Q. -- are they making statements similar to what 03:21:59PM 16 you're making? 17 A. Yes, to all those categories. 18 Q. And you heard the 30(b)(6). 19 Did the government's own witness say that 20 GOJO, the instigator of this entire action, was making 03:22:06PM 21 statements it found to be violative? 22 A. Yes, and not only that, but the statements 23 were made on consumer Web sites, like Amazon; the 24 statements said "FDA-approved"; the statements were made 25 on advertisements that went out to the general public. 03:22:19PM</p>	<p>1 Q. To the best of your knowledge, is the USAID a 2 government agency? 3 A. Yes. 4 Q. Is the FDA a government agency? 5 A. Yes. 03:23:38PM 6 Q. Did you rely upon what the USAID, as part of 7 the federal government, said about your product? 8 A. Yes. 9 Q. Showing what you next what we'll have marked 10 as Exhibit No. 26, can you take a look at that exhibit. 03:24:03PM 11 (Defendants' Exhibit 26 was marked 12 for identification by the court 13 reporter and is bound separately.) 14 BY MR. BEHRE: 15 Q. This is a page -- actually two pages from the 03:24:11PM 16 U.S. Department of Education's Web site as of 17 August 21st, 2019, at 8:57 a.m. 18 The heading of this page from the Department 19 of Education Web site is "Guidance for Schools and 20 Districts About Ebola." 03:24:30PM 21 And I ask you to look at the middle of the 22 page where the guidance says something about encouraging 23 you to convey this information. 24 Do you see that entry? 25 A. I do. 03:24:42PM</p>
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<p>1 Q. Now, showing you what we'll have marked as 2 Exhibit 25, this is a USAID press release. It's dated 3 December 12th, 2014. It was pulled off the archived Web 4 site of the USAID on December 23rd, 2019. 5 (Defendants' Exhibit 25 was marked 03:22:50PM 6 for identification by the court 7 reporter and is bound separately.) 8 BY MR. BEHRE: 9 Q. Have you seen that press release before? 10 A. Yes. 03:22:57PM 11 Q. Are you familiar with the verbiage in the 12 second bullet in the middle of the page that says 13 "Aquarius GEP, LLC, and Innovative BioDefense"? 14 Do you see that? 15 A. Yes, I do. 03:23:09PM 16 Q. And could you read into the record what it 17 says about your company. 18 A. The title is "Aquarius GEP, LLC, and 19 Innovative BioDefense," and it says: 20 "Antiseptic that, when applied to 03:23:20PM 21 skin, provides up to six hours of 22 pathogen protection and serves as 23 antimicrobial barrier to viral 24 transmission for health care 25 workers." 03:23:31PM</p>	<p>1 Q. And what is it that the U.S. Department of 2 Education is encouraging its school leaders to do 3 regarding the prevention of the spread of Ebola? 4 A. (Reading:) 5 "We encourage you to convey this 03:24:53PM 6 information to your district and 7 school leaders and remind teachers, 8 students, and others to," bullet 9 point, "wash hands often with soap 10 and water or alcohol-based hand 03:25:03PM 11 sanitizer," bullet point, "above 12 touching" -- "avoid touching eyes, 13 nose, or mouth," bullet point, "avoid 14 close contact with those who are 15 already sick," bullet point, "get 03:25:16PM 16 plenty of sleep," bullet point, "eat 17 healthy food and drink plenty of 18 fluids," bullet point, "cover your 19 nose and mouth when coughing or 20 sneezing with a tissue or the crook 03:25:26PM 21 of your arm," bullet point, "stay 22 home if you are ill for at least 23 24 hours after the fever is gone." 24 Q. And to the best of your knowledge, is the U.S. 25 Department of Education a government agency, just like 03:25:38PM</p>

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<p>1 A. Well, we've done much -- much more and much</p> <p>2 better scientific studies over the last five years than</p> <p>3 competitors.</p> <p>4 We have an ability to kill for a longer period</p> <p>5 of time and provide benefits as compared to those 03:31:24PM</p> <p>6 competitors in actual real-world studies.</p> <p>7 We've shown better ability to reduce</p> <p>8 infections and illness, um, and we're not allowed to say</p> <p>9 any of those things if we follow what the FDA is telling</p> <p>10 us. 03:31:44PM</p> <p>11 And yet our competitors are reporting that</p> <p>12 they kill in all those environments, sometimes with</p> <p>13 studies that aren't even statistically significant or</p> <p>14 controlled or real world or the same treatment from the</p> <p>15 control arm to the regular arm. 03:31:58PM</p> <p>16 In other words, the studies are not nearly as</p> <p>17 good, and yet they're out making them, and we can't make</p> <p>18 any statements at all.</p> <p>19 I get asked this all the time by our</p> <p>20 salespeople who have been in the industry for years, and 03:32:12PM</p> <p>21 I tell them they can't do this.</p> <p>22 They say, "Well, why not? I've done this all</p> <p>23 my life with all of the products I've ever sold. We're</p> <p>24 allowed to give people peer-reviewed published papers</p> <p>25 and tell them what it says, and we're allowed to 03:32:24PM</p>	<p>1 professionals.</p> <p>2 Q. What use was made of that document?</p> <p>3 A. That document was intended to educate</p> <p>4 ourselves so we could keep everything straight about all</p> <p>5 the studies we were doing, to educate our salespeople in 03:33:43PM</p> <p>6 case they needed to answer a question, like I was asked</p> <p>7 today of what study was this.</p> <p>8 If I look at the technical summary, I can tell</p> <p>9 you what study we relied on for certain things, and then</p> <p>10 if somebody had -- a scientific person had a question 03:33:58PM</p> <p>11 they needed more detail on, that could be provided, but</p> <p>12 only under a confidentiality agreement.</p> <p>13 Q. Has IBD ever owned ZylastDirect.com?</p> <p>14 A. No.</p> <p>15 Q. Has IBD ever operated ZylastDirect.com? 03:34:11PM</p> <p>16 A. No.</p> <p>17 Q. Has IBD ever had the ability to make</p> <p>18 alterations directly to ZylastDirect.com?</p> <p>19 A. No.</p> <p>20 Q. Has IBD ever had the ability to direct a Web 03:34:27PM</p> <p>21 master to make changes to ZylastDirect.com?</p> <p>22 A. No.</p> <p>23 Q. Notwithstanding what you just said, has IBD</p> <p>24 ever encouraged the owner of ZylastDirect.com to make</p> <p>25 changes requested by the FDA? 03:34:42PM</p>
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<p>1 educate," and I say, "I don't know. That's what the FDA</p> <p>2 tells us."</p> <p>3 Q. Did IBD ever sell its product for use with</p> <p>4 Ebola?</p> <p>5 A. No. And you know what's interesting about 03:32:34PM</p> <p>6 that is I easily could have. I know the heads of</p> <p>7 government in most of these places in Africa. I know</p> <p>8 the people -- Doctors Without Borders. I know the</p> <p>9 people at SIM that do this.</p> <p>10 We've got very close relationships. If we had 03:32:50PM</p> <p>11 wanted to sell it for Ebola, we could have in a</p> <p>12 heartbeat, and we never made a single phone call to do</p> <p>13 that.</p> <p>14 Q. Is Zylast Direct -- I'm sorry.</p> <p>15 Is Zylast.com intended for consumers? 03:33:00PM</p> <p>16 A. No.</p> <p>17 Q. Who is the target audience of that Web site?</p> <p>18 A. The target audience is health care</p> <p>19 professionals and risk managers, school nurses, people</p> <p>20 that have to make decisions about infection control in 03:33:17PM</p> <p>21 their environment.</p> <p>22 Q. And is the Zylast technical summary that you</p> <p>23 saw earlier today from counsel -- was that intended for</p> <p>24 consumers?</p> <p>25 A. No. That's not even intended for 03:33:29PM</p>	<p>1 A. Yes. As I testified here today, I informed</p> <p>2 them the changes the FDA would like them to make.</p> <p>3 Q. And why did you do that?</p> <p>4 A. Because it appeared as if the FDA was not --</p> <p>5 wanted those changes made and had not talked to 03:34:55PM</p> <p>6 ZylastDirect.com, and so we finally felt that we should</p> <p>7 at least inform Zylast Direct that the FDA was unhappy</p> <p>8 with those statements.</p> <p>9 Q. You testified at counsel's questions about the</p> <p>10 USAID press release that your company issued. 03:35:11PM</p> <p>11 Do you remember that?</p> <p>12 A. I do.</p> <p>13 Q. Did the USAID review your press release before</p> <p>14 you issued it?</p> <p>15 A. It was provided to them before we issued it, 03:35:20PM</p> <p>16 and they actually took portions of it out and put it on</p> <p>17 their Web site, and they provided theirs to us before</p> <p>18 they issued it.</p> <p>19 Q. And is the USAID part of the federal</p> <p>20 government? 03:35:33PM</p> <p>21 A. Yes, it is.</p> <p>22 Q. And did you -- did you believe you could rely</p> <p>23 upon USAID and their review of your press release?</p> <p>24 A. I did, and in addition to that, HHS was part</p> <p>25 of the review process, as was CDC, and they all were 03:35:44PM</p>

EXHIBIT 2

1 UNITED STATES DISTRICT COURT
2 FOR THE CENTRAL DISTRICT OF CALIFORNIA
3 SOUTHERN DIVISION

4 UNITED STATES OF AMERICA,)
5)
6 Plaintiff,)
7 vs.) No. 8:18 CV 996-DOC(JDE)
8 INNOVATIVE BIODEFENSE,)
9 INC., et al.,)
10 Defendants.)
11 _____)

11 DEPOSITION OF HOTAN BAROUGH
12 TAKEN ON AUGUST 15, 2019
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24 REPORTED BY:

25 PATRICIA L. HUBBARD, CSR #3400

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<p>1 the testimony. He didn't say it was necessary.</p> <p>2 BY MR. ROSS:</p> <p>3 Q. Why did you consider F.D.A. approval?</p> <p>4 A. There was, you know, some products in the</p> <p>5 market that had a bad reputation, and we didn't want</p> <p>6 to be falling into that category.</p> <p>7 Q. What do you mean by "bad reputation"?</p> <p>8 A. They were just performing these balance</p> <p>9 and flexibility tests which I thought were ridiculous.</p> <p>10 And it was a wristband. So, automatically they kind</p> <p>11 of threw us in that category.</p> <p>12 Q. Who is "they"?</p> <p>13 A. Our consumers or potential consumers. Our</p> <p>14 customers, I should say.</p> <p>15 Q. Is Ion Me a significant part of your</p> <p>16 income?</p> <p>17 A. It used to be.</p> <p>18 Q. But no longer?</p> <p>19 A. No. I mean very small amount, yeah.</p> <p>20 Q. Are you otherwise employed besides Ion Me?</p> <p>21 A. Self-employed, yes.</p> <p>22 Q. And what employment is that?</p> <p>23 A. Zylast Direct. Now I help my -- well, my</p> <p>24 father's semi retired, so I am transitioning into</p> <p>25 taking over his business.</p>	<p>1 A. The customers?</p> <p>2 Q. Direct from customers?</p> <p>3 A. Correct.</p> <p>4 Q. Does Zylast send you orders to be</p> <p>5 fulfilled?</p> <p>6 A. I used to get wholesale orders that -- I'm</p> <p>7 not sure where they would get it from, but I would</p> <p>8 fulfill those.</p> <p>9 Q. And how were you paid for your work in</p> <p>10 selling these products?</p> <p>11 A. I would get a small percentage of the</p> <p>12 sales.</p> <p>13 Q. From Zylast?</p> <p>14 A. I would populate a report of the amount</p> <p>15 of -- or the items that were sold, the quantity of the</p> <p>16 items that were sold, and then I would be invoiced for</p> <p>17 it.</p> <p>18 Q. How frequently would you get these</p> <p>19 invoices?</p> <p>20 A. I would get them monthly.</p> <p>21 Q. The orders you were fulfilling of Zylast</p> <p>22 products actually came from a company called</p> <p>23 Innovative BioDefense; is that correct?</p> <p>24 A. Correct.</p> <p>25 Q. And can we agree that I.B.D. would be an</p>
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<p>1 Q. Transitioning from --</p> <p>2 A. Zylast Direct.</p> <p>3 Q. And why are you transitioning out?</p> <p>4 A. Because you guys are coming after me, and</p> <p>5 it's affecting my income.</p> <p>6 Q. Before the lawsuit by F.D.A. was Zylast</p> <p>7 Direct your major income source?</p> <p>8 A. It was.</p> <p>9 Q. Can you tell me more about what Zylast</p> <p>10 Direct is?</p> <p>11 A. We just fulfill products -- or fulfilled</p> <p>12 orders for the Zylast products through our websites --</p> <p>13 or I should say our website and Amazon.com.</p> <p>14 Q. How do you get the orders that you're</p> <p>15 fulfilling for Zylast?</p> <p>16 A. I'm not sure I understand the question.</p> <p>17 Q. You say you fulfill orders for Zylast.</p> <p>18 A. Uh-huh.</p> <p>19 Q. How does that work? Can you explain?</p> <p>20 A. Customers would go to either Amazon.com or</p> <p>21 ZylastDirect.com and place an order. And I would get</p> <p>22 an email alert, and I would fulfill that order. I'd</p> <p>23 pull, pack and ship it.</p> <p>24 Q. From whom do you get the orders that you</p> <p>25 fulfill?</p>	<p>1 appropriate abbreviation for Innovative BioDefense?</p> <p>2 A. Yes.</p> <p>3 Q. You mentioned that you had fulfilled</p> <p>4 wholesale -- used to fulfill wholesale orders.</p> <p>5 What do you mean by that?</p> <p>6 A. I would get packing slips from Gail, her</p> <p>7 last name starts with an M. I believe it's</p> <p>8 Montenegro. I believe they were based in New York.</p> <p>9 And I would basically do the same thing;</p> <p>10 pull the orders, pack them and use the shipping labels</p> <p>11 that they provided to send it out. And I would get a</p> <p>12 commission for that.</p> <p>13 Q. Did Gail Montenegro work for I.B.D.?</p> <p>14 MR. BEHRE: Objection. Vague.</p> <p>15 THE WITNESS: I don't know exactly her</p> <p>16 relationship. I'm assuming. I don't know.</p> <p>17 BY MR. ROSS:</p> <p>18 Q. Do you continue today to fulfill wholesale</p> <p>19 orders?</p> <p>20 A. I haven't gotten them for a while, no.</p> <p>21 Q. Do you know why that is?</p> <p>22 A. I don't.</p> <p>23 Q. Can you be more specific about what the</p> <p>24 "while" has been since you fulfilled wholesale orders?</p> <p>25 A. I wouldn't be able to give you an exact,</p>

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1 but maybe a couple months.

2 Q. Do you know who is fulfilling those
3 wholesale orders that you are no longer doing?

4 A. I don't.

5 MR. BEHRE: Objection. Foundation.
6 Assumes that there are wholesale sales.

7 BY MR. ROSS:

8 Q. You mentioned that you get monthly
9 invoices from I.B.D. for your fulfillment activity.

10 MR. ROSS: Let me ask the court reporter
11 to mark this as Exhibit 1.

12 (Whereupon the document referred
13 to was marked Plaintiff's
14 Exhibit 1 by the Certified
15 Shorthand Reporter and is attached
16 hereto.)

17 BY MR. ROSS:

18 Q. Looking at what's been marked Exhibit 1,
19 can you identify that document?

20 A. This looks to be a packing slip.

21 Q. And you mentioned that packing slips were
22 sent to you by Gail Montenegro?

23 A. Yes.

24 Q. So, can you tell whether this is one that
25 she would -- had sent you?

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1 A. This looks a lot different than the ones
2 that I'm used to seeing.

3 Q. Okay. So, what does it tell us? What is
4 it doing?

5 MR. BEHRE: Objection. Foundation. He
6 said this doesn't look like the type he sees.

7 THE WITNESS: Oh, no. This is not a --
8 this is not a packing slip.

9 BY MR. ROSS:

10 Q. How do you know that?

11 A. Because this doesn't look like a -- this
12 is not a packing slip. It's an invoice, actually.

13 But this is from a long time ago, and it
14 doesn't look very familiar. So I'm assuming this is
15 an invoice that --

16 MR. BEHRE: There's no question
17 outstanding. So let him ask his question.

18 THE WITNESS: Okay.

19 BY MR. ROSS:

20 Q. It's identified as an invoice, is it not?

21 A. Yes.

22 Q. And it says "Bill to Zylast Direct Care of
23 Ion Me."

24 That's the company you mentioned earlier?

25 A. Yes.

1 Q. When did you, to the best of your
2 recollection, start working with I.B.D. to sell Zylast
3 products?

4 A. I don't remember the exact -- it's kind of
5 embarrassing, but I don't even remember the exact
6 year. I'd say right around this time, maybe 2013,
7 '14.

8 Q. Did Zylast Direct have a website?

9 A. Yes.

10 Q. Did you help in creating the website?

11 A. No.

12 Q. What was your role vis-a-vis the website
13 when you first took it over?

14 A. I had no role.

15 Q. Meaning what?

16 A. I'm sorry. I'm not understanding the
17 question.

18 Q. There was a website at some point when you
19 were taking over Zylast Direct.

20 A. Okay.

21 Q. Did you do anything to that website when
22 you formally became --

23 A. No. I just --

24 Q. -- the owner of Zylast Direct?

25 A. I just changed it over to my servers.

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1 Q. And to the best of your recollection, when
2 did you take over Zylast Direct?

3 A. Again I don't know the exact date or year
4 even.

5 Q. But it was sometime before this Exhibit 1
6 date --

7 A. Yes.

8 Q. -- of June 30, 2014?

9 A. Yes. Must have been.

10 Q. When you took over the Zylast Direct
11 website, did you look at the contents?

12 A. I'm assuming, yeah, I did, yeah.

13 Q. Why do you say you assume it?

14 A. It was -- I mean I was very busy with
15 other things, and it was more -- it wasn't very
16 substantial at the time. So I didn't really put too
17 much effort into, you know, spending a lot of time on
18 Zylast Direct when it first started, when I first got
19 involved.

20 Q. You said you were busy with other things.
21 What were those other things?

22 A. My other company.

23 Q. Ion Me?

24 A. Yes.

25 Q. Over time has -- since you were involved

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<p>1 in it as well as Zylast Direct, has Ion Me become more 2 or less profitable for you? 3 A. Less. 4 Q. Do you know why? 5 MR. BEHRE: Objection as to relevance. 6 You can answer, but -- 7 THE WITNESS: I mean it's -- there's a few 8 different reasons. I'm assuming, but it's all 9 speculation. 10 BY MR. ROSS: 11 Q. Well, you say there are a few different 12 reasons. 13 What would they be? 14 A. The market, you know, the amount of time I 15 spent, you know, trying to build it and grow the 16 company, the brand. I'd say those are the two major 17 ones. 18 Q. Does that mean that you spent less time on 19 Ion Me than you did on Zylast Direct over time? 20 A. Yes. Well, eventually. 21 Q. So, did you devote yourself to Zylast 22 Direct as time went on? 23 A. Not fully, but it took a -- a good portion 24 of my time in my, you know, working life. 25 Q. Can you be more specific about a good</p>	<p>1 factors that caused the shutdown? 2 A. Yeah. Then I got an email from Amazon 3 saying that there was an issue with the F.D.A. and -- 4 I don't know -- the products. I'm not too sure what 5 it was. 6 Q. Do you recall hearing about a June 30, 7 2015 warning letter from the F.D.A. to I.B.D.? 8 A. Not until later on. During that time I 9 did not hear about it, no. 10 Q. When you say "later on," can you recollect 11 how much after June 30, 2015 that it was issued that 12 you became aware of it? 13 A. I don't remember the exact time, but I 14 would say months. I don't know exactly. 15 Q. So, as best you can recall, you didn't get 16 notice from I.B.D. about the warning letter? 17 A. Myself? 18 Q. Right. 19 A. I don't remember how I became aware of it. 20 Q. Do you recall whether any customers asked 21 you about it? 22 A. Yeah. 23 Q. What's your recollection of that? 24 A. I just remember a customer inquiring about 25 it.</p>
Page 22	Page 24
<p>1 portion of your time? 2 A. I wouldn't know how to answer that. 3 Q. Can you give an order of magnitude as a 4 percentage of your time, working time? 5 A. During what period? 6 Q. You said over time that you spent a good 7 portion of your time on Zylast Direct. 8 A. Towards the end, yes. Towards -- you 9 know, right around -- well, before this -- all this 10 stuff happened. 11 Q. And by "this stuff," what are you 12 referring to? 13 A. Me being sued and having Amazon or a 14 portion of the business shut down. 15 Q. When you say you being sued, you're 16 referring to the Amended Complaint in this case that 17 was filed on August 27, 2018; is that correct? 18 A. When -- when Amazon was shut down, I 19 believe that was in July of last year. 20 Q. What reasons, if any, do you know led 21 Amazon to shut down the business? 22 A. Initially it was due to, I believe -- the 23 emails that I got was due to late shipments. 24 Q. And you say "initially." 25 Was there something beyond the initial</p>	<p>1 Q. Do you recall the time frame? 2 A. I don't. 3 Q. Do you remember the customer's name? 4 A. I do not. 5 Q. What was your response when a customer 6 asked about it, if you recall? 7 A. I don't remember exactly. 8 Q. Okay. 9 MR. ROSS: Let me ask the court reporter 10 to mark this as Exhibit 2. 11 (Whereupon the document referred 12 to was marked Plaintiff's 13 Exhibit 2 by the Certified 14 Shorthand Reporter and is attached 15 hereto.) 16 MR. BEHRE: It's two sided? 17 MR. ROSS: Right. 18 BY MR. ROSS: 19 Q. Let me know when you've had a chance to 20 look it over. 21 A. I have. 22 Q. Do you recognize this exhibit? 23 A. Yes. 24 Q. What is it? 25 A. It's an invoice.</p>

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<p>1 Q. And it's for what month?</p> <p>2 A. November.</p> <p>3 Q. Of what year?</p> <p>4 A. 2015.</p> <p>5 Q. You said you did not at first, at least,</p> <p>6 recognize Exhibit 1, which was June 30, 2014.</p> <p>7 A. Uh-huh.</p> <p>8 Q. Did the Exhibit 2 start a new format that</p> <p>9 you recognize?</p> <p>10 A. Yes.</p> <p>11 Q. And can you explain what the format is, I</p> <p>12 guess, on the second page that helps you recall this</p> <p>13 one and not Exhibit 1, as well?</p> <p>14 A. This format is the one that I've been</p> <p>15 getting, I mean for the longest time.</p> <p>16 Q. And if we had each of these monthly</p> <p>17 invoices, would we be able to figure out what your</p> <p>18 income was from Zylast Direct?</p> <p>19 MR. BEHRE: Objection. Calls for</p> <p>20 speculation.</p> <p>21 THE WITNESS: An estimate of the -- the</p> <p>22 gross, yes.</p> <p>23 BY MR. ROSS:</p> <p>24 Q. Is this no netting out of expenses or</p> <p>25 other costs on this invoice?</p>	<p>1 A. Overhead for warehousing, offices.</p> <p>2 Q. Anything else?</p> <p>3 A. Yeah. There's plenty of things, yeah.</p> <p>4 Telephone, servers, you know, monthly subscriptions</p> <p>5 for security. A lot of things.</p> <p>6 Q. Where was the warehouse that you used as</p> <p>7 Zylast Direct?</p> <p>8 A. Which warehouse?</p> <p>9 Q. You mentioned warehousing costs would be</p> <p>10 part of your overhead.</p> <p>11 A. Okay.</p> <p>12 Q. Where -- what warehouse?</p> <p>13 A. Which one --</p> <p>14 Q. Where would they be? Where were they?</p> <p>15 A. The first one? I've had three.</p> <p>16 Q. Okay. Where were they located?</p> <p>17 A. Well, initially it was a storage unit that</p> <p>18 I would keep my Ion Me things, and I would use that.</p> <p>19 That was very temporary towards the beginning. And</p> <p>20 then in Costa Mesa at my office and warehouse there.</p> <p>21 Q. Costa Mesa was the initial one or the</p> <p>22 second one?</p> <p>23 A. The first I guess substantial one, yeah.</p> <p>24 The one that, you know, was a little bit more</p> <p>25 expensive.</p>
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<p>1 A. I'm sorry. I'm not understanding.</p> <p>2 Q. You say it would give you the gross</p> <p>3 amount.</p> <p>4 A. Correct. An estimate of the gross amount.</p> <p>5 Q. An estimate. I'm sorry.</p> <p>6 A. Yeah.</p> <p>7 Q. What more information is needed to get to</p> <p>8 the net?</p> <p>9 A. Well, Amazon charges a fee on product and</p> <p>10 shipping. And it's 15 percent.</p> <p>11 Q. Okay.</p> <p>12 A. So --</p> <p>13 Q. What else?</p> <p>14 A. That's why there's a higher percentage on</p> <p>15 the Amazon one to cover that. And then three percent</p> <p>16 is -- well, a little bit more than three percent</p> <p>17 merchant fees for credit card processing on the Zylast</p> <p>18 Direct. So, that's why it's at 13.</p> <p>19 Q. So you would pay both Amazon and credit</p> <p>20 card companies more than is reflected here?</p> <p>21 A. Absolutely.</p> <p>22 Q. Anything else that would be necessary to</p> <p>23 understand how to get to net from these invoices?</p> <p>24 A. And cost of doing business.</p> <p>25 Q. Like?</p>	<p>1 Q. So, first you had the storage unit in --</p> <p>2 A. That we ran --</p> <p>3 Q. -- that Ion Me used?</p> <p>4 A. Correct.</p> <p>5 Q. Where was that?</p> <p>6 A. It was -- well, we had a few of them for</p> <p>7 Ion Me. And then the last one where that transition</p> <p>8 was, I would say -- I think it was in Irvine Public</p> <p>9 Storage.</p> <p>10 Q. Okay. And then you said a second one --</p> <p>11 A. Costa Mesa.</p> <p>12 Q. -- was in Costa Mesa?</p> <p>13 Was that a warehouse as opposed to a</p> <p>14 storage unit?</p> <p>15 A. Yes.</p> <p>16 Q. And then there was a third one?</p> <p>17 A. Los Angeles.</p> <p>18 Q. Do you still have a warehouse today?</p> <p>19 A. I do not.</p> <p>20 Q. When did you close down the Los Angeles</p> <p>21 warehouse?</p> <p>22 A. January.</p> <p>23 Q. Of this year?</p> <p>24 A. Yes.</p> <p>25 Q. Why was that?</p>

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<p>1 A. Because a significant amount of the</p> <p>2 revenue that was coming in was gone because of the</p> <p>3 Amazon account being shut down. So, I -- I moved to</p> <p>4 Orange County, and I work out of the I.B.D. warehouse</p> <p>5 to save costs.</p> <p>6 Q. Where is the I.B.D. warehouse?</p> <p>7 A. In Irvine.</p> <p>8 Q. You said a significant amount of revenue</p> <p>9 was gone.</p> <p>10 How much would you say that was?</p> <p>11 A. I mean as you can see here (indicating) --</p> <p>12 well, this doesn't reflect really what it was towards</p> <p>13 the end.</p> <p>14 Q. You're pointing to Exhibit 2 --</p> <p>15 A. Yeah. But --</p> <p>16 Q. -- on the second page?</p> <p>17 A. I just looked at it right now since it was</p> <p>18 such a long time ago. The Amazon sales are less than</p> <p>19 the Zylast Direct, which is definitely not what it was</p> <p>20 towards the end. I would say about 60 to 70 percent</p> <p>21 of the sales came from Amazon.</p> <p>22 Q. When, to the best of your recollection,</p> <p>23 did that percentage change?</p> <p>24 A. In July when it shut down.</p> <p>25 Q. So, the December 15, 2015 invoice is</p>	<p>1 A. I don't know his title with I.B.D., but he</p> <p>2 works with I.B.D.</p> <p>3 Q. What, if you know, did Mr. Cozean do with</p> <p>4 these records after you sent them to them?</p> <p>5 A. I'm not sure.</p> <p>6 Q. Did they connect in any way to the</p> <p>7 invoices?</p> <p>8 A. Yes. I believe so.</p> <p>9 Q. And what is your belief based on?</p> <p>10 A. I would send these, letting them know how</p> <p>11 many products I've sold for that particular month, and</p> <p>12 they would invoice me.</p> <p>13 Q. Was your practice of sending these reports</p> <p>14 something different in years after 2015, for example?</p> <p>15 This is a September 30, 2018 report.</p> <p>16 When did these reports begin, if you</p> <p>17 remember?</p> <p>18 A. When did I start sending reports?</p> <p>19 Q. Yes.</p> <p>20 A. On how many I sold?</p> <p>21 Q. Right.</p> <p>22 A. I believe from the beginning.</p> <p>23 Q. From the beginning. So they always were a</p> <p>24 precursor to the invoices that we looked at?</p> <p>25 A. Correct.</p>
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<p>1 showing still a smaller percentage from Amazon than</p> <p>2 from Zylast Direct?</p> <p>3 A. Correct.</p> <p>4 Q. When did that change?</p> <p>5 A. I believe it was gradually. I don't know</p> <p>6 exactly the dates or when that started to increase.</p> <p>7 MR. ROSS: Let me ask the court reporter</p> <p>8 to mark this Exhibit 3.</p> <p>9 (Whereupon the document referred</p> <p>10 to was marked Plaintiff's</p> <p>11 Exhibit 3 by the Certified</p> <p>12 Shorthand Reporter and is attached</p> <p>13 hereto.)</p> <p>14 THE WITNESS: Thank you.</p> <p>15 BY MR. ROSS:</p> <p>16 Q. Let me know when you've had a chance to</p> <p>17 look that over. It's also two-sided.</p> <p>18 A. Yes.</p> <p>19 Q. Can you recognize this exhibit?</p> <p>20 A. This is a monthly report that I sent.</p> <p>21 Q. And whom did you send it to?</p> <p>22 A. I usually send it to Jesse.</p> <p>23 Q. Last name?</p> <p>24 A. Cozean.</p> <p>25 Q. Who is that?</p>	<p>1 Q. Okay. So, directing your attention back</p> <p>2 to the Exhibit 2, can you confirm that that's an</p> <p>3 invoice with the Bates number on the back of the</p> <p>4 exhibit 2650, IBC_2650.</p> <p>5 A. I'm sorry. What was the question?</p> <p>6 Q. Can you confirm that I.B.D. page Bates</p> <p>7 numbered IBD_2650 --</p> <p>8 A. IBD_2650.</p> <p>9 MR. BEHRE: It's that number in the lower</p> <p>10 left-hand corner.</p> <p>11 BY MR. ROSS:</p> <p>12 Q. I'm sorry.</p> <p>13 A. Sorry about that. I apologize.</p> <p>14 Q. My fault. Can you confirm that that's an</p> <p>15 invoice --</p> <p>16 A. Yes, that's an invoice.</p> <p>17 Q. And that is the kind of invoice that was</p> <p>18 created by I.B.D. --</p> <p>19 A. Yes.</p> <p>20 Q. -- from the reports that you would send to</p> <p>21 I.B.D.?</p> <p>22 A. Yes.</p> <p>23 Q. And an example of that would be this</p> <p>24 Exhibit 3 that we're looking at?</p> <p>25 A. Yes.</p>

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<p>1 A. Yes.</p> <p>2 Q. -- had a chance to review it?</p> <p>3 Do you recall this email?</p> <p>4 A. I don't.</p> <p>5 Q. This is another example, is it not, of</p> <p>6 Jesse Cozean suggesting the addition of a promo code?</p> <p>7 A. I believe this to be that, yes.</p> <p>8 Q. Did anyone besides Jesse ask that you add</p> <p>9 a promotional code?</p> <p>10 A. I don't remember.</p> <p>11 Q. Okay.</p> <p>12 MR. ROSS: Let's have this marked as</p> <p>13 Exhibit 7, please.</p> <p>14 (Whereupon the document referred</p> <p>15 to was marked Plaintiff's</p> <p>16 Exhibit 7 by the Certified</p> <p>17 Shorthand Reporter and is attached</p> <p>18 hereto.)</p> <p>19 THE WITNESS: Thank you.</p> <p>20 BY MR. ROSS:</p> <p>21 Q. Do you recognize this document?</p> <p>22 A. I don't.</p> <p>23 Q. Do you have any recollection of</p> <p>24 this "Fighting Ebola" code being added to the website?</p> <p>25 A. I don't.</p>	<p>1 BY MR. ROSS:</p> <p>2 Q. Directing your attention to the top email</p> <p>3 Jesse.Cozean@gmail, December 11, 9:01 P.M., do you see</p> <p>4 the first line "Sheryl/Jonathan"?</p> <p>5 A. I do.</p> <p>6 Q. Do you have any recollection of who those</p> <p>7 individuals are?</p> <p>8 A. No.</p> <p>9 Q. Does the name "Sheryl Perez" mean anything</p> <p>10 to you?</p> <p>11 A. Yes.</p> <p>12 Q. What is the context?</p> <p>13 A. I believe she was the person who created</p> <p>14 the Zylast Direct website, or developed it, designed</p> <p>15 and developed it.</p> <p>16 Q. What is your belief based on?</p> <p>17 A. Just my memory. It was a long time ago.</p> <p>18 But --</p> <p>19 Q. Was she working at your direction to</p> <p>20 create the website?</p> <p>21 A. No.</p> <p>22 Q. At whose direction was she working at the</p> <p>23 time, if you know?</p> <p>24 A. I don't.</p> <p>25 Q. How about the name "Jonathan"? Does that</p>
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<p>1 Q. So, directing your attention to the bottom</p> <p>2 of the page, December 11, 2014 at 12:50 P.M. from</p> <p>3 Jesse Cozean, wrote,</p> <p>4 "Can we create a ten percent coupon</p> <p>5 code for this opportunity 'Fighting</p> <p>6 Ebola.' Thanks Jesse."</p> <p>7 You see that?</p> <p>8 A. I do.</p> <p>9 MR. BEHRE: Objection.</p> <p>10 BY MR. ROSS:</p> <p>11 Q. You have no recollection --</p> <p>12 MR. BEHRE: Objection. Foundation. The</p> <p>13 witness has said he doesn't recognize the document.</p> <p>14 And two, that's not an accurate quote of what's typed</p> <p>15 here. It's gobbledegook.</p> <p>16 I'm sure that's a word. I'm not sure how</p> <p>17 to spell it, though.</p> <p>18 Let me clarify. The word is scrambled.</p> <p>19 And Doug has read it like it's a real word.</p> <p>20 MR. ROSS: I beg to differ in part. I</p> <p>21 didn't try to read the ampersand Q-U equal sign T</p> <p>22 portion. But otherwise I didn't make anything up.</p> <p>23 And this is the way you were produced --</p> <p>24 that you produced the documents out of his files.</p> <p>25 ///</p>	<p>1 name mean anything to you?</p> <p>2 MR. BEHRE: Objection. Asked and</p> <p>3 answered.</p> <p>4 THE WITNESS: I don't know.</p> <p>5 BY MR. ROSS:</p> <p>6 Q. Okay.</p> <p>7 A. I mean I'm being honest. I don't know why</p> <p>8 you're laughing, but I'm being honest.</p> <p>9 Q. Let the record reflect I'm not laughing.</p> <p>10 MR. BEHRE: Your colleague was.</p> <p>11 THE WITNESS: No. She was.</p> <p>12 MS. HOANG: I wasn't laughing.</p> <p>13 THE WITNESS: I saw you laughing.</p> <p>14 MR. ROSS: Can you mark that as Exhibit 7,</p> <p>15 please.</p> <p>16 THE REPORTER: Did you say Exhibit 7?</p> <p>17 This is Exhibit 8.</p> <p>18 MR. ROSS: Did I mark 7 already?</p> <p>19 Yes. You're right. Of course.</p> <p>20 (Whereupon the document referred</p> <p>21 to was marked Plaintiff's</p> <p>22 Exhibit 8 by the Certified</p> <p>23 Shorthand Reporter and is attached</p> <p>24 hereto.)</p> <p>25 THE WITNESS: Thank you.</p>

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<p>1 A. Zylast Direct website has a Buy Now --</p> <p>2 Q. Yes.</p> <p>3 MR. BEHRE: Objection. Foundation.</p> <p>4 You might have misspoke. You said Zylast</p> <p>5 Direct.</p> <p>6 THE WITNESS: Zylast.com or Zylast Direct?</p> <p>7 BY MR. ROSS:</p> <p>8 Q. I'm sorry. Zylast.com.</p> <p>9 MR. ROSS: Thank you, Counsel.</p> <p>10 THE WITNESS: How did I come about that?</p> <p>11 BY MR. ROSS:</p> <p>12 Q. Do you know how that connection to Zylast</p> <p>13 Direct came about?</p> <p>14 A. I don't.</p> <p>15 Q. Okay. So, looking at 7984 and the</p> <p>16 highlighted banner portion that's about three quarters</p> <p>17 of the way down the page --</p> <p>18 A. Yes.</p> <p>19 Q. "Zylast is 100 times more effective</p> <p>20 against Norovirus, the stomach flu,</p> <p>21 than a" --</p> <p>22 And the rest of it is not included.</p> <p>23 A. Uh-huh.</p> <p>24 Q. Do you know what the rest of it says, by</p> <p>25 the way?</p>	<p>1 MR. ROSS: I think that's all I have.</p> <p>2 MR. BEHRE: Okay. I've got a few.</p> <p>3</p> <p>4 EXAMINATION</p> <p>5 BY MR. BEHRE:</p> <p>6 Q. Would you please take back Exhibit 34 that</p> <p>7 you just placed down.</p> <p>8 A. Yes.</p> <p>9 Q. Government's Exhibit number 34 is what was</p> <p>10 just shown you.</p> <p>11 Do you have that in front of you now?</p> <p>12 A. Yes.</p> <p>13 Q. And it purports to be a series of</p> <p>14 screenshots of the website that you own, Zylast</p> <p>15 Direct, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Could you please look through this exhibit</p> <p>18 and tell us whether any of those screenshots still</p> <p>19 exist on your website?</p> <p>20 And that would be pages 7980 through 86.</p> <p>21 Just through 86.</p> <p>22 A. Oh. No. No.</p> <p>23 Q. Are any of your statements still on your</p> <p>24 website sitting here today?</p> <p>25 A. No.</p>
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<p>1 A. I don't know.</p> <p>2 Q. Do you know the support for that</p> <p>3 statement?</p> <p>4 A. I do not.</p> <p>5 Q. Do you know how this language got on the</p> <p>6 website?</p> <p>7 A. I don't.</p> <p>8 Q. Have you read it before?</p> <p>9 MR. BEHRE: Objection. Vague and</p> <p>10 ambiguous as to what "it" is. The website?</p> <p>11 BY MR. ROSS:</p> <p>12 Q. Have you read this statement before?</p> <p>13 A. I don't remember.</p> <p>14 MR. BEHRE: I'll also object to this</p> <p>15 exhibit because that is a wrap-around banner, and you</p> <p>16 haven't captured the banner. There's more to the</p> <p>17 statement, as you can see that it's cut off.</p> <p>18 So, this is an incomplete document.</p> <p>19 BY MR. ROSS:</p> <p>20 Q. Did you ever ask anybody at I.B.D. for</p> <p>21 support of this statement?</p> <p>22 A. No. What do you mean by "support of this</p> <p>23 statement"?</p> <p>24 Q. Scientific support for this statement.</p> <p>25 A. Oh, no. No.</p>	<p>1 Q. Now, you testified earlier that you were</p> <p>2 not a salesperson, correct?</p> <p>3 A. Correct.</p> <p>4 Q. You didn't try to convince people to buy</p> <p>5 the Zylast product; is that correct?</p> <p>6 A. Correct.</p> <p>7 Q. And your job was only to fill orders that</p> <p>8 were placed; is that correct?</p> <p>9 A. Correct.</p> <p>10 Q. Were you aware before you learned about</p> <p>11 the warning letter that the F.D.A. purportedly</p> <p>12 regulates Zylast products?</p> <p>13 A. I'm sorry. Can you ask that question</p> <p>14 again? I'm sorry.</p> <p>15 Q. Were you aware at any point before you</p> <p>16 learned about the warning letter that the F.D.A.</p> <p>17 purported to regulate Zylast products?</p> <p>18 A. No.</p> <p>19 Q. Has the F.D.A. ever contacted you at any</p> <p>20 point about your website Zylastdirect.com?</p> <p>21 A. No.</p> <p>22 Q. Has the F.D.A. ever contacted you about</p> <p>23 Zylast products in general?</p> <p>24 A. No. Never.</p> <p>25 Q. Has the F.D.A. ever contacted you about</p>

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<p>1 I.B.D.?</p> <p>2 A. Never.</p> <p>3 Q. Have you ever at any time for any reason</p> <p>4 spoken with or met with anyone from the F.D.A. before</p> <p>5 today when you met F.D.A. counsel?</p> <p>6 A. Never.</p> <p>7 Q. And other than this lawsuit, did you ever</p> <p>8 receive any communication, written or email or</p> <p>9 otherwise, from the F.D.A. about anything?</p> <p>10 A. Yes.</p> <p>11 Q. What was that?</p> <p>12 A. I got a voicemail, I forget from who --</p> <p>13 F.D.A.?</p> <p>14 Q. Yes.</p> <p>15 A. No. Not the F.D.A.</p> <p>16 Q. Excluding --</p> <p>17 A. Doug, I think -- I think Doug was the only</p> <p>18 one.</p> <p>19 Q. He's Department of Justice.</p> <p>20 A. Okay. So, no, I have not.</p> <p>21 Q. And if you had been aware that F.D.A. had</p> <p>22 concerns and wanted you to remove statements from your</p> <p>23 website, what would you have done?</p> <p>24 A. Exactly what I did.</p> <p>25 MR. ROSS: Objection. Hypothetical.</p>	<p>1 regulations?</p> <p>2 A. Absolutely not.</p> <p>3 Q. Do you intend to violate F.D.A.</p> <p>4 regulations in the future?</p> <p>5 A. No. Of course not.</p> <p>6 Q. Did you intend to violate any F.D.A.</p> <p>7 regulations in the past?</p> <p>8 A. Of course not.</p> <p>9 Q. Does your website contain any statements</p> <p>10 whatsoever now?</p> <p>11 A. No.</p> <p>12 Q. And in making decisions about what to</p> <p>13 remove from your website, did you take direction from</p> <p>14 I.B.D.?</p> <p>15 A. Yes.</p> <p>16 Q. Did you take down every statement they</p> <p>17 requested you to make?</p> <p>18 A. Yes.</p> <p>19 MR. BEHRE: That's all I have.</p> <p>20 MR. LEE: Let's go off the record for a</p> <p>21 second.</p> <p>22 (Brief recess.)</p> <p>23 MR. ROSS: We have no further questions.</p> <p>24 This deposition is concluded.</p> <p>25 ///</p>
Page 126	Page 128
<p>1 BY MR. BEHRE:</p> <p>2 Q. And what was it you did?</p> <p>3 A. I took everything off the website.</p> <p>4 Q. Before you were sued by the Government did</p> <p>5 you receive any notice of any intent to sue you?</p> <p>6 A. From --</p> <p>7 Q. Let me rephrase it.</p> <p>8 Did anybody from the Government contact</p> <p>9 you and say "we're going to sue you" before they sued</p> <p>10 you?</p> <p>11 A. No. Absolutely not.</p> <p>12 Q. And you've testified about the warning</p> <p>13 letter.</p> <p>14 Do you recall that?</p> <p>15 A. Yes.</p> <p>16 Q. Is that warning letter addressed to you?</p> <p>17 A. No.</p> <p>18 Q. Are you named in the warning letter in the</p> <p>19 header as an addressee?</p> <p>20 A. No.</p> <p>21 Q. Did the F.D.A. ever mail you that warning</p> <p>22 letter?</p> <p>23 A. No.</p> <p>24 Q. Was it ever your intent that your website</p> <p>25 would make any statements that violate F.D.A.</p>	<p>1 (Whereupon at 2:08 P.M. the</p> <p>2 deposition proceedings were</p> <p>3 concluded.)</p> <p>4 * * *</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

EXHIBIT 3

Table 1

Warning Letter – Labeling claims found on www.zylastdirect.com or www.zylastdirect.com	Still on Website? (Y/N)	Date FDA last documented the statement
“Zylast products are specifically formulated to be effective against a broad spectrum of germs to include bacteria (including drug-resistant bacteria such as MRSA), viruses, molds, fungi, and more.”	N	4/28/2015 – zylastdirect.com . The following statement was on zylastdirect.com as of 3/12/19: “Zylast products are specifically formulated to be effective against a broad spectrum of germs, including bacteria, viruses, fungi, molds, and more.”
“Zylast has been shown to be more than 100 times more effective than alcohol alone, killing 99.97% of Norovirus on contact!”	N	2/22/2016 – zylastdirect.com (“Zylast has been shown to be 100 times more effective than alcohol sanitizers against the Norovirus



Warning Letter – Labeling claims found on www.zylast.com or www.zylastdirect.com	Still on Website? (Y/N)	Date FDA last documented the statement
“Is Zylast effective against the Norovirus (stomach flu)? Zylast has been shown to be 100 times more effective than alcohol sanitizers against the Norovirus (stomach flu) killing 99.97% on contact.”	N	2/22/2016 – zylastdirect.com (stomach flu) killing 99.97% on contact.”
“Is Zylast effective against viruses? Yes! ... BZT and the Zylast actives have also been shown to kill more than 99% of the Rhinovirus (common cold), Rota virus (diarrhea, especially in children), H1N1, Influenza, HIV, and Herpes virus on contact.”	N	2/28/2016 – zylastdirect.com
“Zylast kills more than 99% of Rhinovirus, the highly contagious ‘common cold’ on contact!”	N	9/18/2015 – zylastdirect.com
“Zylast kills influenza, ‘the flu’ and killed 99.99% of the H1N1 strain in 15 seconds!”	N	4/28/2015 – “Zylast kills influenza, ‘the flu’ and killed 99.99% of the H1N1 strain in 15 seconds! It is also 100 times more effective than alcohol-based sanitizers against the stomach flu.” 9/22/2015 – zylastdirect.com (“Zylast was shown

Warning Letter – Labeling claims found on www.zylastdirect.com or www.zylastdirect.com	Still on Website? (Y/N)	Date FDA last documented the statement
		to kill 99.99% of the H1N1 strain in 15 seconds! It is also 100 times more effective as alcohol alone against the stomach flu.”
“Zylast Reduces Illness Outbreaks in Schools by 87.5%!”	N, but “Reducing Illness Outbreak by 87.5%” was on zylast.com as of 8/21/2019.	4/28/2015 – zylast.com
“Zylast was tested against MRSA out to six hour after application, with both products destroying more than 90% of MRSA one hour after they had been applied”	N	7/1/2015 – zylast.com
“Zylast Eliminates: Norovirus (The Stomach Flu) 99.97% ... E. coli 99% ... MRSA & VRE 99% ... Cold & Flu Viruses 99%”	N	7/1/2015 – zylastdirect.com
“The active ingredient in Zylast, BZT ... and is considered safe and effective in concentrations of 0.1-0.2% by the FDA.”	N	5/9/2018

Table 2

Warning Letter – Labeling claims found on Twitter at https://twitter.com/zylastxp	Still on Website? (Y/N)	Date FDA last documented the claim
“Zylast is more than 100 times as effective against the Norovirus as alcohol sanitizers . . .”	N. The Twitter page was no longer available when FDA attempted to access it on 4/22/19.	3/17/2019
“#Zylast is the ONLY hand sanitizer effective in kill (sic) the #flu and #MRSA”	N. The Twitter page was no longer available when FDA attempted to access it on 4/22/19.	3/19/2019

Table 3

Warning Letter – Labeling claims found on Facebook at www.facebook.com/ZylastXP	Still on Website? (Y/N)	Date FDA last documented the claim
“Zylast: New Antibacterial Cleanser May Help Knock Out Ebola”	N. The Facebook page was no longer available when FDA attempted to access it on August 26, 2019.	7/1/2015
“New Zylast article picked up by Sound Medicine at NPR- a potential new tool in the fight against Ebola and disease. Powerful enough for Ebola, safe enough for your family!”	N. The Facebook page was no longer available when FDA attempted to access it on August 26, 2019.	7/1/2015

Table 4

Warning Letter – The Face book page, www.facebook.com/ZylastXP , includes a link to a press release titled “Zylast™ Wins USAID ‘Fighting Ebola Grand Challenge’” (http://www.pmnewswire.com/news-releases/zylast-wins-usaid-fighting-ebola...). Labeling claims found within the press release:	Still on Website? (Y/N)	Date FDA last documented the claim
“The persistence of Zylast is critical in fighting the spread of Ebola. If a healthcare worker comes into contact with an infected person- even one who has not been diagnosed, Zylast provides defense against infection.”	N. The Facebook page was no longer available when FDA attempted to access it on August 26, 2019.	5/29/2019
“Zylast kills any Ebola virus that comes into contact with Zylast-treated skin and will persist up to 6 hours after application.”	N. The Facebook page was no longer available when FDA attempted to access it on August 26, 2019.	5/29/2019
“Zylast is more than 100 times as effective against the Norovirus as alcohol sanitizers ...”	N/A. This claim was included under this section of the Warning Letter by error. As indicated by the Warning Letter and in Table 2, above, this claim was on the Twitter page, not the Facebook page.	See Table 2
“... #Zylast is the ONLY hand sanitizer effective in kill the #flu and #MRSA”	N/A. This claim was included under this section of the Warning Letter by error. As	See Table 2

Warning Letter – The Face book page, www.facebook.com/ZylastXP , includes a link to a press release titled “Zylast™ Wins USAID ‘Fighting Ebola Grand Challenge’” (http://www.pnnewsire.com/news-releases/zylast-wins-usaid-fighting-ebola...). Labeling claims found within the press release:	Still on Website? (Y/N)	Date FDA last documented the claim
	indicated by the Warning Letter and in Table 2, above, this claim was on the Twitter page, not the Facebook page.	

Table 5

Examples of Claims Referenced by the June 6, 2018 Complaint	Still on Website? (Y/N)	Date FDA last documented the claim
<p>“According to the Zylast products’ labeling, including information and hyperlinks on www.zylastdirect.com and www.zylastdirect.com, and the Facebook and Twitter pages referenced in paragraph 10, the Zylast products are intended to be used as topical antiseptics that are effective against the stomach flu and the common cold, and against infection by pathogens that include, but are not limited to, norovirus, rhinovirus, rotavirus, flu virus, Methicillin-Resistant Staphylococcus Aureus bacteria, and/or Ebola virus.” (Compl., ¶ 19).</p>	<p>Examples of claims referenced in paragraph 19 of the Complaint were listed in the Amended Complaint. See Tables 6 and 7 below for the status of each claim. Examples of claims referenced in paragraph 19 of the Complaint were also listed in the Plaintiff’s Responses to Defendants IBD’s and Dr. Cozean’s First Set of Interrogatories, see Tables 8 – 11 below for the status of each claim.</p>	<p>See Tables 6 – 11.</p>
<p>“In addition, as late as June 19, 2017, the Zylast products’ labeling also contained claims that they were effective against H1N1, HIV, herpes, and Vancomycin-resistant enterococci bacteria.” (Compl., ¶ 19).</p>	<p>N</p>	<p>6/19/2017</p>
<p>“The Zylast products’ labeling, http://www.zylastdirect.com/safety, contains the following statement: “Zylast have [sic] an unmatched safety profile. The active ingredient in Zylast, BZT . . . is even considered safe and effective in open wounds by the FDA.” (Compl., ¶ 24).</p>	<p>N</p>	<p>7/9/2018</p>

Examples of Claims Referenced by the June 6, 2018 Complaint	Still on Website? (Y/N)	Date FDA last documented the claim
“Zylast Has an Unmatched Safety Profile . . . the active ingredient in Zylast, BZT, . . . is considered safe and effective for first aid in concentrations of 0.1-0.2% by the FDA.” (Compl., ¶ 24).	N	5/9/2018

Table 6

Amended Complaint (Aug. 27, 2018) – Statements or materials from www.zylast.com, ¶ 20	Still on Website? (Y/N)	Date on which FDA last documented the claims	Has Gov't Discussed Statement with Defendants?¹
Zylast has been able to “successfully combat the spread of infection”	N	11/6/2018	See FN1
Zylast is “[s]hown to Kill >99% of Norovirus surrogate ² ”	N	11/6/2018	See FN1
“Beth McNichol, PhD . . . Zylast Lotion is effective against pathogens like the Norovirus, rotavirus, and the common cold – some of the most prevalent diseases among children”	N	11/6/2018	See FN1
“Clinical Benefit: Shown to reduce hospital infections by 23.1%, illness in schools by 39%, and illness outbreaks by almost 90%”	N. But the following statements were on zylast.com as of August 21, 2019: “In clinical studies, Zylast has reduced illness in hospitals, nursing homes, and schools . . . Proven Clinical Benefit . . . In a study in hospitals . . .	11/6/2018	See FN1

¹ Defendants’ 30(b)(6) notice asks for this information only with respect to the website statements cited in the Amended Complaint. The answer is no. The Government has not discussed these specific statements with Defendants, because there is no requirement that the Government give Defendants notice of which labeling statements it intended to include in the Amended Complaint. In any event, FDA has already issued notice, including through the June 30, 2015 Warning Letter, that Defendants’ claims that the Zylast products are effective against or in reducing or preventing disease by pathogens such as norovirus, MRSA, Ebola, etc. are evidence that such products are new drugs.

Amended Complaint (Aug. 27, 2018) – Statements or materials from www.zylast.com , ¶ 20	Still on Website? (Y/N)	Date on which FDA last documented the claims	Has Gov't Discussed Statement with Defendants? ¹
	Zylast reduced hospital acquired infections (HAIs) by 20% . . . Reducing Illness in Nursing Home . . . In a clinical study, alcohol-based sanitizers . . . were replaced with persistent Zylast antiseptic. Making this change significantly reduced nosocomial infections. Overall infections were down by 17%, with significant reduction in upper respiratory tract infections, ears/eyes/nose/throat infections, and other infections.”		
A video titled “Dr. Steve discusses Zylast” that discusses Zylast Antiseptic Lotion as effective against the norovirus as well as 100% of other bacteria like E-coli that can cause diarrhea, vomiting, and stomach cramps	N	10/31/2018	See FN1
An assertion that Zylast was the “[w]inner of the Fighting Ebola Grand Challenge”	N	10/31/2018	See FN1

Table 7

Amended Complaint (Aug. 27, 2018) – Statements or materials from www.zylastdirect.com , ¶ 21	Still on Website? (Y/N)	Date on which FDA last documented the claims	Has Gov't Discussed Statement with Defendants?¹
“Designed to prevent infection in hospitals, nursing homes, schools, and at home, Zylast is a unique antimicrobial technology”	N.	10/31/2018	See FN1
“The extended protection against transient MRSA of the Zylast products has also been evaluated using human skins substitutes in-vitro . . . Zylast reduced transient MRSA by 100% at 2 minutes after being applied and washed off . . .”	N. But as of March 12, 2019, zylastdirect.com contained a bar graph titled “Persistent Reduction of MRSA” that suggested, <i>inter alia</i> , that “Zylast Soap” was effective in reducing MRSA by 100% after 2 minutes.	10/31/2018	See FN1
“Zylast is 100 times more effective against Norovirus ‘the stomach flu’”	N	10/31/2018	See FN1
“Zylast is effective against Influenza ‘the flu’, Rhinovirus ‘the common cold’ . . .”	N	3/11/2019	See FN1
“There are three primary reasons for the reduction in illness with the Zylast technology . . . Zylast Lotion is effective against pathogens like the Norovirus, rotavirus, and the	N	3/11/2019	See FN1

Table 8

Plaintiff's Responses to Defendants IBD's and Dr. Cozean's First Set of Interrogatories at 14-18) – "Statements (other than those listed in the Amended Complaint) found on zylast.com as recently as November 6, 2018 [GOV-00001960-1967]"	Still on Website? (Y/N)	Date FDA last documented the claim
"Winner Fighting Ebola Grand Challenge: Because of persistent efficacy, testing against viruses, and clinical studies showing a reduction in illness outbreaks, Zylast was awarded a winner by experts from the CDC, USAID, and Pentagon as a 'breakthrough innovation' in hand hygiene."	N	11/6/2018
"Zylast has been shown to reduce illness in hospitals, nursing homes, and schools."	N. But the following statement was on zylast.com as of August 19, 2019: "In clinical studies, Zylast has reduced illness in hospitals, nursing homes, and schools."	11/6/2018
"Zylast Foaming Soap showed substantially better persistent effect when tested against both E. Coli (gram negative) and MRSA (gram positive) bacteria in testing"	Y	8/19/2019
"Testimonial . . . Annie Pryor, PhD, Stop the Stomach Flu . . . Zylast Antiseptic is a very exciting hand sanitizer that kills the norovirus surrogate Feline calicivirus 99.97%"	Y	08/19/2019

Table 9

Plaintiff's Responses to Defendants IBD's and Dr. Cozcan's First Set of Interrogatories at 14-18) – "Statements (other than those listed in the Amended Complaint) found on zylastdirect.com as recently as October 31, 2018 [GOV-00001917-1940]."	Still on Website? (Y/N)	Date FDA last documented the claim
"Zylast is one of the winners of the grand challenge to fight ebola"	N	10/31/2018
"Persistent Reduction of MRSA . . . The extended protection against transient MRSA of the Zylast products has also been evaluated using human skins substitutes in-vitro . . . Zylast reduced transient MRSA by 100% at 2 minutes after being applied and washed off";	N	10/31/2018
Defendants' suggestion that Zylast is different because it is effective against viruses and drug resistant bacteria such as MRSA and VRE: "About Zylast . . . And so the Zylast journey began . . . [S]oap and water, and alcohol-based sanitizers kill some bacteria, but after careful research they were disappointed to find no sound data that showed they were effective against viruses and drug resistant bacteria such as MRSA and VRE."	N	3/12/2019
A hyperlink to an article titled "Westmont First to Adopt Zylast Sanitizer for a New Level of Campus Clean," with the following statements, among others, in the article: "It has also been successfully tested against the Rotavirus, a common cause of diarrhea among children, and Rhinovirus, the common cold. The active ingredient in Zylast, BZT, has been shown to kill more than 99 percent of other viruses like influenza, HIV and Herpes on contact . . . initial contact with the school came through IBD's President, Dr. Colette Cozcan, a Westmont alumna"	N	10/31/2018
A hyperlink to an article titled "Zylast products show antimicrobial persistence," with the following statements, among others, in the article:	N	10/31/2018

<p>“Two of the most prevalent and dangerous of these drug-resistant bacteria are Methicillin-Resistant <i>S. aureus</i> (MRSA) and Vancomycin-Resistant Enterococci (VRE). Testing was performed with the Zylast antiseptic against both of these deadly bacteria. Not only did the antiseptic destroy more than 99.99% of these bacteria on contact, it was still killing more than 90% of VRE and MRSA one hour after it was applied . . . Previous testing has also been performed against the H1N1 flu, where the Zylast Antiseptic killed 99.99% of the virus within 15 seconds. Innovative BioDefense, creators of Zylast, believe the combination of increased immediate kill and long-lasting persistence can significantly reduce infection rates in hospitals, nursing homes, schools, and businesses.”</p>		
<p>A hyperlink to an article titled “Antimicrobial Hand Sanitizer best on the Market,” with the following statements, among others, in the article: “Innovative BioDefense, the creators of the ZylastXP Antiseptic Foaming Soap . . . has announced that recent tests show that more than 99.99 percent of disease-causing germs were destroyed within 15 seconds . . . Three types of Zylast products were tested against a range of 25 different bacteria . . . Testing was also done on <i>S. aureus</i> (MRSA) and vancomycin-resistant Enterococci (VRE). In both incidents, the product destroyed more than 99.99 percent of these bacteria on contact and killed more than 90 percent of both VRE and MRSA one hour later. The Norovirus was another target for the Zylast antiseptic product. It was shown to be more than 100 times more effective against Norovirus than alcohol alone.”</p>	N	3/1/2019

Table 10

Plaintiff's Responses to Defendants IBD's and Dr. Cozean's First Set of Interrogatories at 14-18) – "Statements or materials found on Defendants' Facebook page, www.facebook.com/ZylastXP, as recently as October 30, 2018 [GOV-00001903-1916]"	Still on Website? (Y/N)	Date FDA last documented the claim
A post with the following statement: "With Zylast winning the National Fighting Ebola Grand Challenge, we want to offer the same protection to all of our customers over the flu season. Head to ZylastDirect.com and use the coupon code FightingEbola to save 10% on Zylast." (present on October 30, 2018, originally posted on December 15, 2014)	N. The Facebook page was no longer available when FDA attempted to access it on August 26, 2019.	5/29/2019
A post with a hyperlink to a press release titled "Zylast™ Wins USAID 'Fighting Ebola Grand Challenge,'" with the following statements, among others, in the press release: "Immediate kill and 6 hour persistence likely to prevent Ebola infections . . . The persistence of Zylast is critical in fighting the spread of Ebola. If a healthcare worker comes into contact with an infected person . . . Zylast provides defense against infection . . . Zylast kills any Ebola virus that comes into contact with Zylast-treated skin . . . Zylast has been proven to kill Norovirus, HIV, Poliovirus, all Influenzae including H1N1, Herpes Simplex, Rhinovirus, Rotavirus, and many others . . . This would confirm the ability of Zylast in conjunction with other protective equipment to reduce Ebola infection . . . 'Zylast has the potential to contain the spread of Ebola,' according to Dr. Beth McNicol, who holds her PhD in Emerging Infectious Disease."	N. The Facebook page was no longer available when FDA attempted to access it on August 26, 2019.	5/29/2019
A post with a hyperlink to an article entitled "Lake Forest company's antiseptic sanitizer may help in Ebola fight" with the following statements, among others, in the article: "Many-layered protective suits help health care workers who are treating patients avoid exposure to Ebola, but each time they disrobe, the risk of infection returns 'Health care workers fighting	N. The Facebook page was no longer available when FDA attempted to access it on August 26, 2019.	5/29/2019

<p>the epidemic in Africa . . . could apply Zylast before donning garb and still be protected against infection during removal' Cozean said."</p>		
<p>A post with a hyperlink to an article entitled "New hand sanitizer might help protect against Ebola" with the following statements, among others, in the article: "There are hand sanitizers, and there are hand sanitizers. A relatively new potent product helps protect against the Norovirus, H1N1 flu virus and the Rotavirus, which is the most common cause of diarrhea in children. But now a product is being tested in the fight against a deadly virus which has recently killed nearly 7,000 people. A new sanitizer could help treat and care for patients with the Ebola virus and health care workers in West Africa. 'The fact that it can be applied before they put the gloves on and their whole suit and still be providing protection when they're taking it off and removing it which is the most dangerous time for healthcare workers,' Jesse Cozean, Vice President of Research and Development at Zylast. The product, called Zylast is already being used in hospitals and schools worldwide" (present on May 8, 2018, originally posted on December 20, 2014).</p>	<p>N. The Facebook page was no longer available when FDA attempted to access it on August 26, 2019.</p>	<p>The post, which included the title of the article, was present as of 5/29/2019. However, the article itself was no longer hyperlinked to the post. The last time FDA accessed the article via a hyperlink from the post was on 5/8/2018.</p>

Table 11

Plaintiff's Responses to Defendants IBD's and Dr. Cozcan's First Set of Interrogatories at 14-18) – "Continued statements or materials on the twitter.com/ZylastXP feed as recently as October 31, 2018 [GOV-00001914-1916]"	Still on Website? (Y/N)	Date FDA last documented the claim
Zylast is more than 100 times as effective against the Norovirus" (present on October 31, 2018, originally posted on July 21, 2014);	N. The Twitter page was no longer available when FDA attempted to access it on 4/22/19.	3/17/2019
"We are making big noise in the world of #infectiousdisease! #Zylast is the ONLY hand sanitizer effective in killing the #flu and #MRSA" (present on October 31, 2018, originally posted on September 29, 2013);	N. The Twitter page was no longer available when FDA attempted to access it on 4/22/19.	3/19/2019
"Zylast Retweeted MRSA INFECTION @ mrsainfection... Zylast products show antimicrobial persistence dlvr.it/3fzYLK #mrsa" (present on October 31, 2018, originally posted on July 16, 2013).	N. The Twitter page was no longer available when FDA attempted to access it on 4/22/19.	3/19/2019

EXHIBIT 4

Attachment 1

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

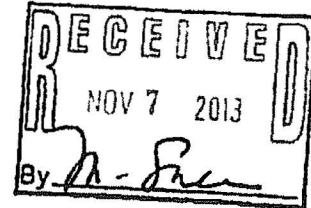
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November 7, 2013



BY HAND DELIVERY

Howard Sklamberg, Esq.
Director, Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration (HFD-300)
10903 New Hampshire Avenue, Room 5270
Silver Spring, Maryland 20993-0002

Dear Mr. Sklamberg:

This is to call your attention to certain over-the-counter (OTC) antimicrobial products that are clearly and blatantly misbranded and unapproved new drugs. These products include Qore Systems' Qore-24™ Antimicrobial Hand Purifier ("More than a Hand Sanitizer") [<http://amosilq.com/qore24.html>], Coating Systems Laboratories, Inc.'s Germ Free 24 Hand Sanitizer and Protectant [www.coatingsystemslaboratories.com/products_germfree.php], and Zylast Antiseptic, Antiseptic Lotion and Foaming Hand Soap (among others), marketed by Innovative Biodefense, Inc. [<http://zylast.com/ZylastStore.aspx>]. These products are promoted and advertised with claims for uses that are not included in the Tentative Final Monograph for Healthcare Antiseptic Drug Products, 59 Fed. Reg. 31,402 (June 17, 1994) (the TFM) and are outside the OTC review for such products. To our knowledge, there are no approved new drug applications in effect for any of the products.

These products join the dozens of violative OTC antimicrobial drugs, and particularly hand sanitizers, to which we have called your office's attention over recent years and which cry out for strong and consistent regulatory action by the Food and Drug Administration (FDA). As noted briefly below, and fully disclosed on the firms' websites, these products are marketed with claims for various trendy bacterial and viral diseases which the agency has expressly stated, on numerous occasions, are not approved or permitted for topical OTC antibacterial drugs. They also blatantly claim to have persistent, leave-on benefits, which the agency has also declared to be unacceptable claims for such products. But unless the agency finally takes broad and effective

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GOV-00000631

Howard Sklamberg, Esq.
November 7, 2013
Page 2

HYMAN, PHELPS & MCNAMARA, P.C.

regulatory action against these and other similarly labeled and promoted violative drugs, the public will remain at risk and the seriousness of the agency's regulatory program for OTC drugs will be open to question.

Specifically, the web site for Qore-24 contains several claims that are not within the TFM or the pending OTC review and which have been the subject of FDA regulation action and/or express statements as to their violative status, such as anti-viral, barrier, persistence and MRSA claims. Examples include:

- "Eliminates 99% of Bacteria, Viruses and Fungus"
- "Forms a 24-Hour Barrier"
- "24 Hour Germ Protection Factor"
- "Creates a safe and protective 24-hour antimicrobial barrier on the skin"
- "Effective against bacteria, fungus, and viruses including: MRSA, VRE, Cdiff, influenza, HIV and H1N1"

And that is just from the first page of the website.

The website for Germ Free 24 similarly promotes that product for use against *viruses and fungi, and claims up to 24 hours of continuous effect. For example, the web site claims:*

- "Germ Free 24 contains the active material AMOSILQ which is not only effective against bacteria, but also viruses and fungi."
- "On application to the skin, Germ Free 24 forms an invisible, odorless, moisturizing layer that will not wash off and continues to be effective against microbial pathogens for up to 24 hours or more."
- "The AMOSILQ film formed on application of Germ Free 24 retains its broad spectrum antiviral, antibacterial and antifungal activity for up to 24 hours or more."

Howard Sklamberg, Esq.
November 7, 2013
Page 3

HYMAN, PHELPS & MCNAMARA, P.C.

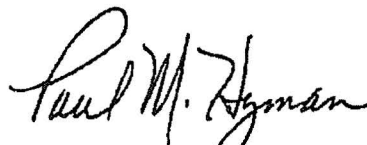
- "Germ Free 24 kills not only bacteria but also viruses and fungi which can cause ringworm, and fungal nail infections."

Comparing Germ Free 24 to other marketed hand sanitizers, the web site further claims the product has "residual germ killing properties," provides "all day protection" [emphasis in original] and an "antimicrobial barrier," and "makes your hands germ fighting machines."

Similar labeling and promotional claims are made for the Zylast products. On every page, the web site prominently states: "Kills 99.99% of germs on contact, persistent for six hours." (Emphasis added.) Subsequent pages emphasize the persistence of the products, with comparisons to alcohol hand sanitizers and other products. Moreover, the products are claimed to be "more than 100 times as effective as alcohol alone against Norovirus," an unapproved use for an OTC antibacterial drug. Other unapproved claims include "reduces hospital infection rates by 44%," as well as specific kill claims for H. influenza, Norovirus and viruses in general.

All of these products thus violate the law and the FDA's regulations and policies. The agency should take prompt and effective regulatory action against these products, to protect the public health and to begin to bring this category of OTC drugs into compliance.

Sincerely,



Paul M. Hyman

PMH/cam

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Qore-24 Antimicrobial Hand Purifier

<http://www.amosilq.com/qore24.html>

Page 1 of 2



WHAT IS AMOSIL-Q? WHY IT MATTERS? WHAT'S YOUR CLEAN-Q? OUR PRODUCTS FAQs



MORE THAN A HAND SANITIZER.

Qore-24™

Antimicrobial Hand Purifier

- Eliminates 99.4% of Bacteria, Viruses and Fungus
- Forms a 24-Hour Barrier
- Non-Toxic and Non-Flammable

BUY NOW
More Info >>



BACK to PRODUCTS

MORE THAN A HAND SANITIZER:

A revolutionary technology for a new era in germ protection.

One application of Qore 24 delivers the same protection as an alcohol-based sanitizer applied every 30 seconds or 2,880 times a day.

ADVANTAGES & BENEFITS

- Creates a safe and protective 24 hour antimicrobial barrier on the skin
- Patented technology instantly sanitizes on contact
- Non-Flammable and Non-Toxic
- Effective against bacteria, fungus, and viruses including MRSA, VRE, Cdiff, Influenza, HIV and H1N1
- One complete list of over 1000 germs killed by Qore 24 on full data sheet
- Maintains the skin and prevents drying, redness, and chapping
- Puts an end to skin to skin transfer of germs
- Not harmful to human or animal life

CLOSE

Qore-24	
Non-Flammable & Non-Toxic	YES
Remains Active After Drying	YES
Forms Protective Barrier on Skin	YES
Remains Active After 10 Washes	YES
Effective for 24 Hours or More	YES
Moisturizes Skin	YES



WHAT IS AMOSIL-Q?



WHY IT MATTERS



WHAT'S YOUR CLEAN-Q?



OUR PRODUCTS

BLOG



- 3 Reasons to Use Qore-24 and Why It Matters
- Qore-24: The New Standard in Hand Sanitization
- Qore-24: The New Standard in Hand Sanitization

VIDEOS & MEDIA



- Qore-24 Testimonial

NEWS & UPDATES



- Qore-24 is the New Standard in Hand Sanitization
- Qore-24 is the New Standard in Hand Sanitization
- Qore-24 is the New Standard in Hand Sanitization

WHAT IS AMOSIL-Q?

WHY IT MATTERS

WHAT'S YOUR CLEAN-Q?

OUR PRODUCTS

VIDEOS & MEDIA

WHERE TO BUY

FAQS

CONTACT US

STORE

BLOG

<http://www.amosilq.com/qore24.html>

11/6/2013

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Coating Systems Laboratories, Inc.

HOME | CONTACT | ABOUT

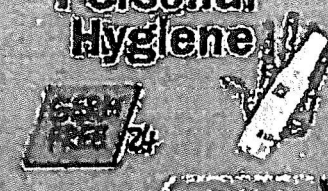
CSL Product Line

Pool Care



MORE

Personal Hygiene




MORE

Microbe Prevention

Zincide

- ANTIACID
- BACTERIOSTAT
- FUNGICIDE

MORE



Hand Sanitizer and Protectant

Promotes and Protects the Health of Those You Care For
ONE SPRAY FOR ALL DAY

Germ Free 24 is a completely unique method of promoting and protecting the health of adults and children. This product is unlike the common alcohol based antibacterial products on the market today as it is formulated with a minimum amount of alcohol and to insure it will not dry the skin and cause redness, chapping and flaking. Alcohol based products on the market today contain greater than 60% alcohol which is a skin irritant, flammable and the persistent use of which has been reported to decrease the ability to fight off infections. Germ Free 24 contains the active material AMOSILO which is not only effective against bacteria but also viruses and fungi. On application to the skin, Germ Free 24 forms an invisible, odorless, moisturizing layer that will not wash off and continues to be effective against microbial pathogens for up to 24 hours or more.

Advantages

- Forms a protective antimicrobial barrier on the skin
- Antimicrobial activity remains through a minimum of ten hand washings
- Sanitizes skin and nails
- Effective against viruses, bacteria and fungi
- Adheres to skin and is effective for up to 24 hours or longer
- Moisturizes the skin and prevents drying, redness and chapping
- Water based product is non-flammable

Benefits

- Provides unsurpassed antimicrobial protection for hands
- Inhibits skin to skin transfer of germs
- Gentle, moisturizing hand sanitizer
- Regular application provides continual antimicrobial protection
- Long lasting protection against pathogenic organisms including viruses, fungi, and bacteria
- Easy, rapid, spray application
- Colorless product is invisible on application and will not stain skin or clothing

Most conventional hand sanitizers are gels comprised of ethyl alcohol in a thickened organic base. Their activity is primarily antibacterial, not antimicrobial and is limited to their presence on the skin which immediately ceases when evaporated from the skin. After application, they leave the skin surface very susceptible to reinfection. Their antibacterial properties are not persistent after application.

Germ Free 24 Hand Sanitizer is a specially formulated product containing the antimicrobial active ingredient, AMOSILO. This active ingredient is unlike any product for topical skin application on the market today. On application to the hands, an antimicrobial, polymeric film is formed which is substantive and will remain through a minimum of ten hand washings. The AMOSILO film formed on

application of Germ Free 24 retains its broad spectrum antiviral, antibacterial and antifungal activity for up to 24 hours or more. It derives its antimicrobial activity through contact with the pathogen and causing disruption of the pathogen's cellular wall, a process termed lysis. The AMOSILO film is not incorporated into the pathogen cell and therefore no increased drug type resistance by the pathogen is acquired. The AMOSILO ingredient contains a silicon material that orients to the skin surface during application to produce a protective, moisturizing film.

The Germ Free product line is state of the art technology and unlike any product available on the market today. AMOSILO, the active ingredient, is totally unique in structure, effectiveness, persistence and application. It is a material which chemically combines proven antimicrobial chemistry with the protective, moisturizing capabilities of silicones in a single molecular compound. The water soluble AMOSILO transforms to an invisible macropolymeric, polyionic layer on application to the skin which is not removed by repeated hand washing or rinsing. Not being removed by water, Germ Free 24 offers continuing antimicrobial protection coupled with long term moisturizing qualities. Germ Free 24 kills not only bacteria, but also viruses and fungi which can cause ringworm, and fungal nail infections. Application to the skin not only kills and inactivates bacteria, viruses and fungi, but also prevents reinfection. Germ Free 24 does not build or increase antibacterial or antimicrobial resistance in pathogens on repeated or prolonged use.

The big difference

The big difference between Germ Free 24 and other hand sanitizers on the market today is the other hand sanitizers are primarily ethyl or isopropyl alcohol formulations which are largely antibacterial in nature. While they will kill selected bacteria on application to the skin, they offer no residual germ killing properties. Application of these products to your hands will not only dry out your skin, they offer a fresh surface for germs to reinfect as soon as your hands are dry. Germ Free 24 is the only product that remains on your hands for all day protection. Germ Free 24 also moisturizes as it protects. The problem with using other hand sanitizer products is that without the antimicrobial barrier provided by Germ Free 24, they just become a new breeding ground for more germs. Germ Free 24 with AMOSILO protects you from all types of germs all day long and actually makes your hands germ fighting machines. This technology is so unique and important that it is patent protected.

U.S. Patent No. 6,613,755 & Patents Pending

Germ free 24 is clear and invisible on the skin when applied. It is nonflammable and will not stain clothing. It contains a small amount of ethyl alcohol to prevent freezing and is phthalate free.

Availability

Germ Free 24 is packaged into 2 ounce and 8 ounce clear plastic bottles each with a finger pump spray





A Revolution in Hand Hygiene
Kills 99.99% of germs on contact, persistent for six hours

PRODUCTS

THE SCIENCE

FAQ'S

NEWS

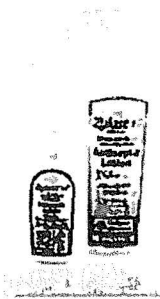
RESOURCES

ABOUT US

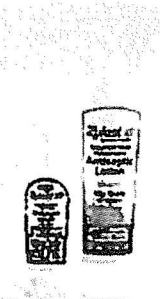
CONTACT US

Zylast Products

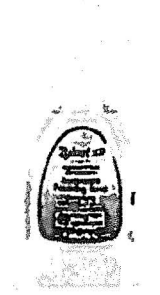
Tested by independent laboratories across the country, Zylast™ is truly a revolution in hand hygiene. After testing the product, researchers at Pace University concluded, "No comparable product is capable of providing the degree of the long term protection exhibited by the Zylast® hand sanitizers."



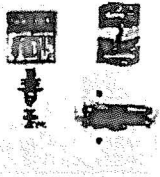
Antiseptic: The Antiseptic is alcohol-based and compliant with CDC recommendations for hospitals, but provides persistent protection for six hours without skin irritation, as proved by independent lab testing. The Antiseptic is recommended for hospitals and offers a substantial improvement over standard, alcohol-based sanitizers by adding persistence, reducing skin irritation, and saving money.



Antiseptic Lotion: Water-based and formulated with high-end emollients and skin-care products, the Antiseptic Lotion feels luxurious on the skin while providing rapid, broad-spectrum kill and persistent protection from germs. The Antiseptic Lotion is an ideal product for schools, long-term care facilities, cruise ships, businesses, and for around the house, providing protection without the downsides of alcohol-based products.



Foaming Hand Soap: The soap is built around patented Zylast technology, not only killing on contact but providing persistent protection for six hours, without the harsh feel of many soaps or the health risks of Triclosan-based products. It is used in bathrooms, at sinks, and in many food-preparation areas.



Surgical Scrub: The surgical scrub is persistent for six hours, exceeds FDA requirements for a surgical scrub, and protects surgeons, staff and patients in the operating room.



Dispensers: All Zylast products are available in sleek, convenient, and ADA-approved dispensers. These come in manual and automatic, and can be wall-mounted or put on a movable stand. Dispensers are calibrated for the perfect shot size for Zylast, saving customers money." We can add the above picture of the manual and auto dispenser next to that one.

BUY NOW

© 2010 Innovative Biodefense, Inc. Patents Pending



For orders call 888-306-0316

<http://zylast.com/ZylastStore.aspx>

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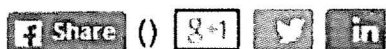
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Attachment 2

Zylast™ Wins USAID "Fighting Ebola Grand Challenge"

Immediate Kill and 6-hour Persistence Likely to Prevent Ebola Infections



LAKE FOREST, Calif., Dec. 12, 2014 /PRNewswire/ -- Zylast™ products have been selected as one of only three initial winners of the USAID Fighting Ebola Grand Challenge. The announcement, made from the White House, introduces Zylast as a solution to "help healthcare workers on the front lines provide better care and stop the spread of Ebola."

The persistence of Zylast is critical in fighting the spread of Ebola. If a healthcare worker comes into contact with an infected person – even one who has not been diagnosed, Zylast provides defense against infection. According to the World Health Organization (WHO), nearly 10% of the casualties of the outbreak have been healthcare workers treating Ebola patients.

Zylast also guards healthcare workers at the critical moments when they remove protective gear, which can be suffocatingly hot and close in West African climates. The riskiest time for healthcare workers is when the equipment comes off, as skin can come into contact with an infected surface. Zylast kills any Ebola virus that comes into contact with Zylast-treated skin and will persist up to 6 hours after application. Alcohol sanitizers have no persistent effect – once they evaporate, skin can immediately become recontaminated, a serious danger in Ebola treatment.

More than 1,500 applications were received for the USAID Fighting Ebola Grand Challenge. The eight-step process was supervised by USAID, with contributions from scientists and experts from key organizations like the Centers for Disease Control (CDC), World Health Organization (WHO) and Department of Defense (DOD).

Zylast is a powerful hand sanitizing technology developed and provided by Innovative BioDefense (IBD), in partnership with Aquarius GEP; it not only kills on contact, but provides persistent protection for 6 hours, and protects the skin from drying and cracking. It is the only hand sanitizer that has been proven to reduce hospital-acquired infections (HAIs) over handwashing alone in a controlled, randomized clinical trial. When used in schools, Zylast prevented nearly 90% of contagious illness and reduced absenteeism by 39%. A major issue in the outbreak is the lack of clean, running water and hand hygiene to prevent transmission.

"We are grateful for this recognition of the life-saving value of our products," said Dr Colette Cozean, CEO of IBD. "Together with our partners at Aquarius GEP, we have a special dedication to the health and welfare of Africa and Africans, and our most important goal is to end this epidemic and to spread health for the suffering people of West Africa."

Zylast kills at least 99.99% of 25 different, FDA-specified germs, and is more than 100 times more effective than common alcohol sanitizers, and does not irritate skin – irritated or dried skin is more susceptible to infection. Zylast has been proven to kill Norovirus, HIV, Poliovirus, all Influenzae including H₁N₁, Herpes Simplex, Rhinovirus, Rotavirus, and many others.

Director of Infection Prevention Amanda Billings, MPH at Physicians for Healthy Hospitals states, "Our hospital has been using Zylast for four months. As an infection preventionist I am always looking for the newest technology that will provide our patients with a safer hospital stay. Zylast's ability to kill viruses and persistent antimicrobial properties are key factors to achieving reduced hospital-acquired infections. The non-irritating property of Zylast is also a positive with the staff and encourages increased hand hygiene compliance."

Following laboratory testing, USAID may authorize a pilot clinical study at several beta sites in high-risk areas of West Africa. This would confirm the ability of Zylast in conjunction with other protective equipment to reduce Ebola infection.

Fast-growing orders surpassing many tens of millions of dollars have already been received by Innovative BioDefense for disaster relief from international crisis relief organizations such as UNICEF, and from the DOD. Zylast can be used throughout West Africa to prevent the spread of the Ebola epidemic by April 2015.

"Zylast has the potential to contain the spread of Ebola," according to Dr. Beth McNicol, who holds her PhD in Emerging Infectious Disease. "It is highly effective on contact against bacteria and enveloped viruses, and it also offers persistent protection for six hours. Zylast provides protection directly on the skin and could significantly impact the fight against Ebola."

The current Ebola outbreak began in December of 2013, and has spread through the West African countries of Guinea, Liberia, and Sierra Leone. More than 18,000 cases have been reported, though the CDC and World Health Organization suggest that the true number could be several times higher. The disease has proven fatal in more than 70% of cases. The Fighting Ebola Grand Challenge offers the opportunity to impact the spread of the disease with practical and innovative technologies.

Zylast can be bought by consumers over the Internet at Amazon, or at numerous other sites. It is also available at www.zylastdirect.com (<http://www.zylastdirect.com/>) (code:FightingEbola).

About Aquarius GEP

Aquarius GEP focuses on commercialization of patented technologies from geothermal/waste heat recovery systems to anti-microbial, anti-pathogen technologies effective at preventing widespread pandemics of infectious disease, including Ebola.

About IBD

Innovative BioDefense Inc. (IBD), manufacturer of the Zylast™ line of persistent antimicrobial products, is headquartered in Lake Forest, CA. Zylast utilizes a unique and patented combination of ingredients to provide rapid, broad-spectrum germ kill with persistence for six hours. The company has a full line of effective, persistent antiseptic products for use by healthcare professionals, businesses and consumers. The Zylast hand

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sanitizer products debuted in October of 2012 and have been proven to reduce illness outbreaks, hospital-acquired infection, and school absenteeism. Products include the water-based Antiseptic Lotion, the alcohol-based Antiseptic and the Foaming Hand Soap, and are available in 2 oz. and 8 oz. bottles as well as wall-mounted dispensers. For more information please visit www.zylast.com (<http://www.zylast.com/>). Products are available to order online at www.zylastdirect.com (<http://www.zylastdirect.com/>). Zylast is a Trademark of Innovative BioDefense.

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SOURCE Innovative BioDefense Inc.

RELATED LINKS

<http://www.zylast.com> (<http://www.zylast.com>)

Attachment 3

Zylast

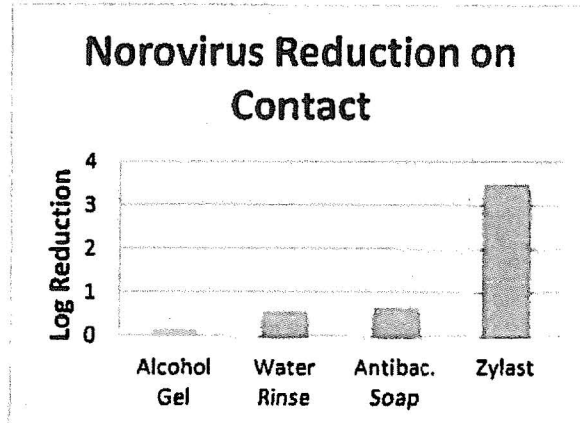
Zylast - Ebola Technical Bulletin for Healthcare Professionals

Viral Kill

The Ebola virus is an enveloped virus, a class of virus that alcohol sanitizers are generally effective against. However, the Zylast products have shown to be significantly more effective against many viruses than traditional alcohol sanitizers. Zylast has been shown to kill 99.97% of the Norovirus on contact,¹ and the Zylast actives destroyed more than 99% of the rhinovirus (common cold) and rotavirus (diarrhea in children),² both viruses that many alcohol sanitizers are relatively ineffective against.

In schools, where viruses spread rapidly among students and teachers, Zylast was shown to prevent nearly 90% of illness outbreaks.³

Zylast also exceeds the European requirements for a virucidal product, passing the EN14476 test for virucidal activity against polio, one of the most difficult viruses to destroy.⁴



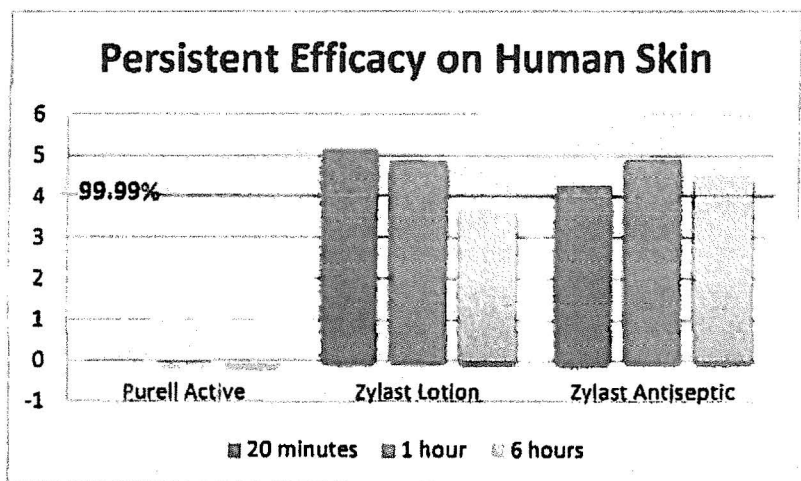
Zylast is shown to be more than 100 times as effective as standard alcohol sanitizer against the hard-to-kill Norovirus surrogate

Persistence

Perhaps the most important aspect of a sanitizer with respect to Ebola is persistence. Standard alcohol sanitizers are only effective for 15 seconds – after that, hands can immediately become contaminated.

With no persistence, healthcare workers can follow all hand hygiene protocols and still become infected. If a nurse “washes in” prior to entering a patient room (if the patient hasn’t been diagnosed yet) and touches the patient, their hands have no protection. If that nurse then touches their face, clothes, or another area of the body they could be exposed to Ebola before leaving the room – even if they have followed their hand hygiene practices perfectly.

Zylast is different, providing persistent protection for six hours after application, in accordance with CDC recommendations for persistent effect.



Zylast killed more than 99.9% of transient pathogens that came into contact with the skin, even after drying.



"(An Antiseptic product should be) broad-spectrum, fast-acting, and if possible, persistent." – CDC Guideline for Hand Hygiene in Healthcare Settings, 2002

Rapid, Broad-Spectrum Kill

The Zylast Antiseptic has been tested against all 25 FDA-specified pathogens, killing more than 99.999% on contact and destroying the germs significantly faster than other alcohol sanitizers.⁵

Clinical Effect

The benefit of the Zylast technology has been proven in clinical studies. It is the only hand sanitizer proven to reduce Hospital-Acquired Infection over handwashing alone in a controlled clinical study, reducing HAIs by 23.1%.⁷ It has also been shown to prevent 87.5% of illness outbreaks in schools.³

	Avagard D Sanitizer ² (61% ethanol)	Zylast Antiseptic (76% ethanol)
<i>S. aureus</i>	99.1%	99.9997%
<i>S. epidermis</i>	>99.9%	99.9996%
<i>K. pneumonia</i>	>99.9%	99.9999%
<i>P. aeruginosa</i>	>99.9%	99.9999%
<i>E. coli</i>	>99.9%	99.9999%
<i>S. pneumonia</i>	>99.9%	99.9999%
<i>S. pyogenes</i>	98.0%	99.9999%
<i>S. marcescens</i>	>99.9%	99.9999%
<i>E. faecalis</i>	>99.9%	99.9999%

The Zylast Antiseptic works faster and kills more completely than other sanitizers. Studies have shown that sanitizers with higher levels of alcohol, like Zylast, are more effective against viruses⁶ like Ebola.

"How do I protect myself against Ebola? Wash hands frequently or use an alcohol-based sanitizer" – CDC Ebola Q&

	Fast-Acting	Broad-Spectrum (Bacteria)	Broad-Spectrum (Viruses)	Acceptance by Personnel	Persistence
Standard Alcohol Sanitizers	✓	✓			
Zylast	✓	✓	✓	✓	✓

References

1. Czerwinski SE, Cozean J, *An evaluation of a Hand Sanitiser Product to Reduce Norovirus Cross Infection*, BGTHA, 20: 42-46, 2012
2. Shintre M et al, *Evaluation of an Alcohol-Based Surgical Hand Disinfectant...*, Infection Control and Hospital Epidemiology, 28(2), 2007
3. Keeney B, Cozean J et al, *Reduction in Illness Absenteeism among Students and Staff with Novel, Water-Based Antiseptic Lotion in Crossover Study*, 2013
4. Canew Testing and Certification, *Evaluation of the Zylast Products using the EN14476 Protocol*, Report CNT1402281221, 11/15/2014
5. Czerwinski SE et al, *Novel water-based Antiseptic Lotion compared with Alcohol Sanitizer Demonstrates Rapid, Broad-Spectrum Kill*, Journal of Infection and Public Health (2014) 7, 199–204
6. CDC Guideline for Hand Hygiene in Health-Care Settings. 2002
7. Cozean J and Kampiatu P, *A controlled, crossover study of a persistent antiseptic to reduce hospital-acquired infection*, AJID (2014) 9(1): 6-9

EXHIBIT 5

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Attorneys for Plaintiff
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

INNOVATIVE BIODEFENSE, INC.,
et al.,

Defendants.

No. 8:18 CV 996-DOC (JDE)

PLAINTIFF'S RESPONSES TO
DEFENDANTS' FIRST SET OF
REQUESTS FOR ADMISSION OF FACT

Plaintiff United States of America ("Plaintiff") provides the following responses to Defendants' First Set of Requests for Admission of Fact.

Request for Admission No. 1: The U.S. Food and Drug Administration ("FDA") received multiple complaints about Innovative BioDefense, Inc. ("IBD") from the law firm of Hyman, Phelps, & McNamara, P.C.

Response to Request for Admission No. 1: Plaintiff objects to the use of the term "multiple" as vague and overbroad. Subject to that objection, Plaintiff admits that Hyman,

1 Phelps, & McNamara, P.C. contacted FDA more than once about IBD.

2
3 **Request for Admission No. 2:** Hyman, Phelps, & McNamara, P.C. contacted the
4 FDA to urge FDA to investigate IBD.

5 **Response to Request for Admission No. 2:** Plaintiff admits that Hyman, Phelps &
6 McNamara contacted FDA to urge FDA to investigate three hand sanitizer manufacturers,
7 including IBD.

8
9 **Request for Admission No. 3:** Hyman, Phelps, & McNamara, P.C. has represented
10 GOJO Industries, Inc.

11 **Response to Request for Admission No. 3:** Admit.

12
13 **Request for Admission No. 4:** The following information contained in the
14 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
15 website: Zylast has been able to “successfully combat the spread of infection.”

16 **Response to Request for Admission No. 4:** Plaintiff objects to the use of the term
17 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
18 referenced statement does not currently appear on the referenced website.

19
20 **Request for Admission No. 5:** The following information contained in the
21 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
22 website: Zylast is “[s]hown to kill >99% of Norovirus surrogate.”

23 **Response to Request for Admission No. 5:** Plaintiff objects to the use of the term
24 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
25 referenced statement does not currently appear on the referenced website.

26
27 **Request for Admission No. 6:** The following information contained in the
28

1 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
2 website: “Beth Nichol, PhD . . . Zylast Lotion is effective against pathogens like the
3 Norovirus, rotavirus, and the common cold – some of the most prevalent diseases among
4 children.”

5 **Response to Request for Admission No. 6:** Plaintiff objects to the use of the term
6 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
7 referenced statement does not currently appear on the referenced website.

8
9 **Request for Admission No. 7:** The following information contained in the
10 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
11 website: “Clinical Benefit: Shown to reduce hospital infections by 23.1%, illness in
12 schools by 39%, and illness outbreaks by almost 90%.”

13 **Response to Request for Admission No. 7:** Plaintiff objects to the use of the term
14 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
15 referenced statement does not currently appear on the referenced website. However,
16 Plaintiff denies that zylast.com does not contain information demonstrating that Zylast
17 products are intended to reduce hospital-acquired infections and infections in hospitals,
18 nursing homes, and schools. *See* Ex. 10 to the deposition of Plaintiff’s 30(b)(6) witness
19 (August 30, 2019).

20
21 **Request for Admission No. 8:** The following information contained in the
22 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
23 website: The video titled “Dr. Steve discusses Zylast.”

24 **Response to Request for Admission No. 8:** Plaintiff objects to the use of the term
25 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
26 referenced video does not currently appear on the referenced website.

1 **Request for Admission No. 9:** The following information contained in the
2 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
3 website: Zylast was the “[w]inner of the Fighting Ebola Grand Challenge.”

4 **Response to Request for Admission No. 9:** Plaintiff objects to the use of the term
5 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
6 referenced statement does not currently appear on the referenced website.

7
8 **Request for Admission No. 10:** The following information contained in the
9 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
10 website: “Designed to prevent infection in hospitals, nursing homes, schools, and at home,
11 Zylast is a unique antimicrobial technology.”

12 **Response to Request for Admission No. 10:** Plaintiff objects to the use of the term
13 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
14 referenced statement does not currently appear on the referenced website.

15
16 **Request for Admission No. 11:** The following information contained in the
17 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
18 website: “The extended protection against transient MRSA of the Zylast products has also
19 been evaluated using human skins substitutes in-vitro . . . Zylast reduced transient MRSA
20 by 100% at 2 minutes after being applied and washed off...”

21 **Response to Request for Admission No. 11:** Plaintiff objects to the use of the term
22 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
23 referenced statement does not currently appear on the referenced website.

24
25 **Request for Admission No. 12:** The following information contained in the
26 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
27 website: “Zylast is 100 times more effective against norovirus ‘the stomach flu’”; “Zylast
28

1 is effective against Influenza ‘the flu,’ Rhinovirus ‘the common cold.’”

2 **Response to Request for Admission No. 12:** Plaintiff objects to the use of the term
3 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
4 referenced statement does not currently appear on the referenced website.
5

6 **Request for Admission No. 13:** The following information contained in the
7 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
8 website: “There are three primary reasons for the reduction in illness with Zylast
9 technology . . . Zylast lotion is effective against pathogens like Norovirus, rotavirus, and
10 the common cold – some of the most prevalent diseases among children. . . Beth
11 McNichol, PhD, Emerging Infectious Disease.”

12 **Response to Request for Admission No. 13:** Plaintiff objects to the use of the term
13 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
14 referenced statement does not currently appear on the referenced website.
15

16 **Request for Admission No. 14:** The following information contained in the
17 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
18 website: “Dr. Steve discusses Zylast” video.

19 **Response to Request for Admission No. 14:** Plaintiff objects to the use of the term
20 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
21 referenced video does not currently appear on the referenced website.
22

23 **Request for Admission No. 15:** The following information contained in the
24 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
25 website: Zylast was “one of the winners” of the “grand challenge to fight ebola.”

26 **Response to Request for Admission No. 15:** Plaintiff admits that the referenced
27 information does not currently appear on the referenced website.
28

1
2 **Request for Admission No. 16:** The following information contained in the
3 Amended Complaint, dated August 27, 2018, does not appear on the www.zylast.com
4 website: Hyperlinks to news articles and other materials allegedly demonstrating that
5 Zylast is intended to be effective against infection by pathogens such as HIV, herpes,
6 Vancomycin-resistant enterococci bacteria (“VRE”).

7 **Response to Request for Admission No. 16:** Plaintiff admits that hyperlinks to
8 news articles and other materials allegedly demonstrating that Zylast is intended to be
9 effective against HIV and herpes do not currently appear on the referenced website.
10 Plaintiff denies that hyperlinks to materials demonstrating that Zylast is intended to be
11 effective against infection, including infection from VRE, do not appear on the referenced
12 website.

13
14 **Request for Admission No. 17:** The website www.zylastdirect.com does not
15 presently contain any promotional statements about Zylast products.

16 **Response to Request for Admission No. 17:** Denied.
17

18 **Request for Admission No. 18:** The website www.zylastdirect.com does not
19 presently contain any statements the Government identified in the Warning Letter, dated
20 June 30, 2015, or the Amended Complaint, dated August 27, 2018.

21 **Response to Request for Admission No. 18:** Admit.
22

23 **Request for Admission No. 19:** The website <https://twitter.com/ZylastXP>
24 referenced in the Amended Complaint no longer exists.

25 **Response to Request for Admission No. 19:** Plaintiff admits that the referenced
26 Twitter page was no longer available when Plaintiff attempted to access it on April 4,
27 2019. *See* Ex. 2 to the deposition of Plaintiff’s 30(b)(6) witness (August 30, 2019).
28

1
2 **Request for Admission No. 20:** The Facebook page at [https://www.facebook.com/](https://www.facebook.com/ZylastXP)
3 ZylastXP referenced in the Amended Complaint no longer exists.

4 **Response to Request for Admission No. 20:** Plaintiff admits that the referenced
5 Facebook page was no longer available when Plaintiff attempted to access it on August
6 26, 2019. *See* Ex. 2 to the deposition of Plaintiff's 30(b)(6) witness (August 30, 2019).
7

8 **Request for Admission No. 21:** In April 2014, FDA employee Heath Harley
9 recommended that no regulatory action be taken against Innovative BioDefense, Inc.

10 **Response to Request for Admission No. 21:** Plaintiff admits that on April 4, 2014,
11 FDA employee Heath Harley sent an email to FDA employee Anuj Shaw stating that "it
12 appears that the [Zylast] products would be violative based on the claims on promotional
13 materials provided (barrier claims, MRSA, time specific protection etc). However, given
14 CDER's competing priorities, I do not recommend regulatory action for this product at
15 this time. These products should be catalogued for the possibility of future regulatory
16 action as an OUDLC initiative." *See* Ex. 1 to deposition of Heath Harley (June 20, 2019).
17

18 **Request for Admission No. 22:** In April 2014, FDA employee Anuj Shah
19 recommended that no regulatory action be taken against Innovative BioDefense, Inc.

20 **Response to Request for Admission No. 22:** Plaintiff admits that on April 18,
21 2014, FDA employee Anuj Shaw responded to the Heath Harley email referenced in
22 request number 21 by concurring with Heath Harley's recommendation. *See* Ex. 1 to
23 deposition of Heath Harley (June 20, 2019).
24

25 **Request for Admission No. 23:** The following information contained in the
26 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
27 www.zylastdirect.com: "Zylast products are specifically formulated to be effective against
28

1 a broad spectrum of germs to include bacteria (including drug-resistant bacteria such as
2 MRSA), viruses, molds, fungi, and more.”

3 **Response to Request for Admission No. 23:** Plaintiff objects to the use of the term
4 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
5 referenced statement does not currently appear on the referenced websites.

6
7 **Request for Admission No. 24:** The following information contained in the
8 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
9 www.zylastdirect.com: “Zylast has been shown to be more than 100 times more effective
10 than alcohol alone, killing 99.97% of Norovirus on contact!”

11 **Response to Request for Admission No. 24:** Plaintiff objects to the use of the term
12 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
13 referenced statement does not currently appear on the referenced websites.

14
15 **Request for Admission No. 25:** The following information contained in the
16 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
17 www.zylastdirect.com: “Is Zylast effective against Norovirus (stomach flu)? Yes! Zylast
18 has been shown to be more than 100 times more effective than alcohol sanitizers against
19 the Norovirus (stomach flu) killing 99.97% on contact.”

20 **Response to Request for Admission No. 25:** Plaintiff objects to the use of the term
21 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
22 referenced statement does not currently appear on the referenced websites.

23
24 **Request for Admission No. 26:** The following information contained in the
25 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
26 www.zylastdirect.com: “Is Zylast effective against viruses? Yes! ... BZT and Zylast
27 actives have also been shown to kill more than 99% of the Rhinovirus (common cold),
28

1 Rota virus (diarrhea, especially in children), H1N1, Influenza, HIV, and Herpes virus on
2 contact.”

3 **Response to Request for Admission No. 26:** Plaintiff objects to the use of the term
4 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
5 referenced statement does not currently appear on the referenced websites.

6
7 **Request for Admission No. 27:** The following information contained in the
8 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
9 www.zylastdirect.com: “Zylast kills more than 99% of Rhinovirus, the highly contagious
10 ‘common cold’ on contact!”

11 **Response to Request for Admission No. 27:** Plaintiff objects to the use of the term
12 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
13 referenced statement does not currently appear on the referenced websites.

14
15 **Request for Admission No. 28:** The following information contained in the
16 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
17 www.zylastdirect.com: “Zylast kills influenza, ‘the flu’ and killed 99.99% of the H1N1
18 strain in 15 seconds!”

19 **Response to Request for Admission No. 28:** Plaintiff objects to the use of the term
20 “information” as vague and overbroad. Subject to that objection, Plaintiff admits that the
21 referenced statement does not currently appear on the referenced websites.

22
23 **Request for Admission No. 29:** The following information contained in the
24 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
25 www.zylastdirect.com: “Zylast Reduces Illness Outbreaks in Schools by 87.5%!”

26 **Response to Request for Admission No. 29:** Denied. As of September 8, 2019,
27 the www.zylast.com website stated that Zylast reduces illness outbreaks in schools by
28

1 87.5%. *See* Ex. 10 to the deposition of Plaintiff's 30(b)(6) witness (August 30, 2019);
2 GOV-00027980.

3
4 **Request for Admission No. 30:** The following information contained in the
5 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
6 www.zylastdirect.com: "Zylast was tested against MRSA out to six hour after application,
7 with both products destroying more than 90% of MRSA one hour after they had been
8 applied."

9 **Response to Request for Admission No. 30:** Plaintiff objects to the use of the term
10 "information" as vague and overbroad. Subject to that objection, Plaintiff admits that the
11 referenced statement does not currently appear on the referenced websites.

12
13 **Request for Admission No. 31:** The following information contained in the
14 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
15 www.zylastdirect.com: "Zylast Eliminates: Norovirus (The Stomach Flu) 99.97% ... E.
16 coli 99% ... MRSA & VRE 99% ... Cold & Flu Viruses 99%."

17 **Response to Request for Admission No. 31:** Plaintiff objects to the use of the term
18 "information" as vague and overbroad. Subject to that objection, Plaintiff admits that the
19 referenced statement does not currently appear on the referenced websites.

20
21 **Request for Admission No. 32:** The following information contained in the
22 Warning Letter, issued June 30, 2015, does not appear on www.zylast.com and
23 www.zylastdirect.com: "The active ingredient in Zylast, BZT ... is considered safe and
24 effective in concentrations of 0.1%-0.2% by the FDA."

25 **Response to Request for Admission No. 32:** Plaintiff objects to the use of the term
26 "information" as vague and overbroad. Subject to that objection, Plaintiff admits that the
27 referenced statement does not currently appear on the referenced websites.

1
2 **Request for Admission No. 33:** Innovative BioDefense, Inc. informed the FDA
3 and DOJ of the changes made to the website zylast.com and zylastdirect.com in a letter
4 dated July 21, 2017.

5 **Response to Request for Admission No. 33:** Plaintiff objects to this request
6 because it is vague in that it does not identify “the changes made to” the referenced
7 websites. Subject to that objection, Plaintiff admits that Defense Counsel’s July 21, 2017
8 letter to FDA and DOJ listed changes that had purportedly been made to the referenced
9 websites.

10
11 **Request for Admission No. 34:** The formulation of Zylast products does not
12 present a public health danger.

13 **Response to Request for Admission No. 34:** Plaintiff can neither admit nor deny
14 this statement because Plaintiff has not tested the formulation of the Zylast products, and
15 therefore, denies it.

16
17 **Request for Admission No. 35:** The June 30, 2015 Warning Letter is addressed to
18 Defendants Innovative BioDefense, Inc. and Collette Cozean but not Hotan Barough.

19 **Response to Request for Admission No. 35:** Admit.

20
21 **Request for Admission No. 36:** The FDA did not directly provide Hotan Barough
22 with any notice regarding potential violations related to his website
23 www.zylastdirect.com, until the Amended Complaint was filed in this case on August 27,
24 2018.

25 **Response to Request for Admission No. 36:** Admit, but Plaintiff also notes that
26 documents produced by Mr. Barough show that Mr. Barough knew about the FDA
27 Warning Letter, which identified statements on www.zylastdirect.com, before Plaintiff
28

1 filed the Amended Complaint. *See, e.g.*, Exs. 25, 28, 30, and 32 to the deposition of Hotan
2 Barough (August 15, 2019).

3
4 **Request for Admission No. 37:** The FDA Regulatory Procedures Manual dated
5 April 2019 encourages the FDA to achieve voluntary and prompt corrective action before
6 initiating an enforcement action.

7 **Response to Request for Admission No. 37:** FDA admits that its Regulatory
8 Procedures Manual states, “When it is consistent with the public protection responsibilities
9 of the agency and depending on the nature of the violation, it is [FDA’s] practice to give
10 individuals and firms an opportunity to take voluntary and prompt corrective action before
11 it initiates an enforcement action,” and it states “FDA is under no legal obligation to warn
12 individuals or firms that they or their products are in violation of the law before taking
13 enforcement action,” and “a Warning Letter is not a prerequisite to taking enforcement
14 action.” *See* Regulatory Procedures Manual at § 4-1-1 (April 2019).

15
16 **Request for Admission No. 38:** The FDA did not contact Hotan Barough regarding
17 any potential violations of the law prior to filing the Amended Complaint on August 27,
18 2018.

19 **Response to Request for Admission No. 38:** Admit, but Plaintiff also notes that
20 documents produced by Mr. Barough show that Mr. Barough knew about the FDA
21 Warning Letter, which identified statements on www.zylastdirect.com, before Plaintiff
22 filed the Amended Complaint. *See, e.g.*, Exs. 25, 28, 30, and 32 to the deposition of Hotan
23 Barough (August 15, 2019).

1
2
3
4
5
6
7 Dated: September 16, 2019

Respectfully submitted,

8 JOSEPH H. HUNT
Assistant Attorney General

9 DAVID M. MORRELL
Deputy Assistant Attorney General

10 GUSTAV W. EYLER
11 Director, Consumer Protection Branch

12 /s/ Douglas Ross

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19 Counsel for the United States of America
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CERTIFICATE OF SERVICE

I hereby certify that on September 16, 2019, I served via email true and correct copies of the foregoing *Plaintiff's Responses to Defendants' First Set of Requests for Admissions of Fact* on the following individuals:

Benjamin A. Nix - ban@paynefears.com
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Marc C. Sanchez - msanchez@fdaatty.com
Contract In-House Counsel & Consultants LLC
d/b/a FDA Atty

s/ Douglas Ross
Douglas Ross

EXHIBIT 6



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
WASHINGTON, D.C. 20580



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD 20993

WARNING LETTER

VIA UNITED PARCEL SERVICE SIGNATURE REQUIRED

June 30, 2015

Dr. Colette Cozean, President/CEO
Innovative Biodefense Inc.
21581 Midcrest Drive
Lake Forest, CA 92630

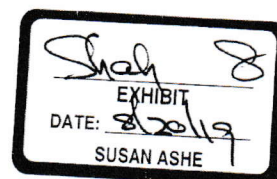
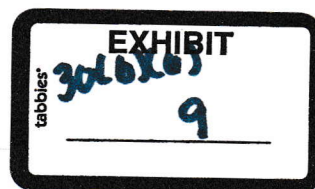
Dear Dr. Cozean:

This letter concerns your firm's marketing of the Zylast antiseptic product line, including Zylast XP Antiseptic, Zylast XP Antiseptic Foaming Soap, and Zylast XP Antiseptic Lotion (collectively, the Zylast products). The United States Food and Drug Administration (FDA) and the United States Federal Trade Commission (FTC) reviewed claims on Zylast product labels and on your website, www.zylast.com, which includes links to the Zylast social-media pages at Facebook and Twitter.

As currently formulated, labeled, and promoted, these products are unapproved drugs in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 355(a)]. Introduction of such products into interstate commerce is prohibited under § 301(d) of the FD&C Act [21 U.S.C. § 331(d)]. These violations are described in more detail below. Please note that this is not inclusive of all the products your firm manufactures and/or distributes and may not represent all product violations.

Unapproved New Drug Charges

Although all three Zylast products have stated purposes as topical "antiseptics," the product labeling states intended uses that cause the products to be unapproved new drugs under section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. This includes website labeling claims for effectiveness against specific serious-disease-related pathogens such as Ebola, Methicillin-Resistant *Staphylococcus aureus* (MRSA), H1N1 flu virus, and norovirus. Furthermore, Zylast XP Antiseptic product labeling indicates



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use as a leave-on product that is not rinsed off. The intended use of a product may be determined by, among other things, its labeling, advertising, and the circumstances surrounding its distribution, 21 CFR § 201.128. Labeling claims demonstrating such intended uses of the Zylast products include, but are not limited to, the following claims made on websites that offer these products for sale:

www.zylast.com and www.zylastdirect.com:

Zylast products (Zylast XP Antiseptic, Zylast XP Antiseptic Foaming Soap, and Zylast XP Antiseptic Lotion):

- "Zylast products are specifically formulated to be effective against a broad spectrum of germs to include bacteria (including drug-resistant bacteria such as MRSA), viruses, molds, fungi, and more."
- "Zylast has been shown to be more than 100 times more effective than alcohol alone, killing 99.97% of Norovirus on contact!"
- "Is Zylast effective against the Norovirus (stomach flu)? Yes! Zylast has been shown to be 100 times more effective than alcohol sanitizers against the Norovirus (stomach flu) killing 99.97% on contact."
- "Is Zylast effective against viruses? Yes! . . . BZT and the Zylast actives have also been shown to kill more than 99% of the Rhinovirus (common cold), Rotavirus (diarrhea, especially in children), H1N1, Influenza, HIV, and Herpes virus on contact."
- "Zylast kills more than 99% of Rhinovirus, the highly contagious 'common cold' on contact!"
- "Zylast kills influenza, 'the flu' and killed 99.99% of the H1N1 strain in 15 seconds!"
- "Zylast Reduces Illness Outbreaks in Schools by 87.5%!"
- "Zylast was tested against MRSA out to six hour after application, with both products destroying more than 90% of MRSA one hour after they had been applied"
- "Zylast Eliminates: Norovirus (The Stomach Flu) 99.97% . . . E. coli 99% . . . MRSA & VRE 99% . . . Cold & Flu Viruses 99%"

Labeling claims found on Twitter at <https://twitter.com/zylastxp>:

- "Zylast is more than 100 times as effective against the Norovirus as alcohol sanitizers..."
- "... #Zylast is the ONLY hand sanitizer effective in kill the #flu and #MRSA"

Labeling claims found on Facebook at https://www.facebook.com/ZylastXP/info?tab=page_info:

- "Zylast: New Antibacterial Cleanser May Help Knock Out Ebola"
- "New Zylast article picked up by Sound Medicine at NPR - a potential new

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tool in the fight against Ebola and disease. Powerful enough for Ebola, safe enough for your family!"

The Facebook page (https://www.facebook.com/ZylastXP/info?tab=page_info) includes a link to a press release titled Zylast™ Wins USAID "Fighting Ebola Grand Challenge" (<http://www.prnewswire.com/news-releases/zylast-wins-usaid-fighting-ebola-grand-challenge-300009163.html>). Labeling claims found within the press release:

- "The persistence of Zylast is critical in fighting the spread of Ebola. If a healthcare worker comes into contact with an infected person – even one who has not been diagnosed, Zylast provides defense against infection."
- "Zylast kills any Ebola virus that comes into contact with Zylast-treated skin and will persist up to 6 hours after application."
- "Zylast is more than 100 times as effective against the Norovirus as alcohol sanitizers..."
- "... #Zylast is the ONLY hand sanitizer effective in kill the #flu and #MRSA"

Labeling claims found on Facebook at https://www.facebook.com/ZylastXP/info?tab=page_info:

- "Zylast: New Antibacterial Cleanser May Help Knock Out Ebola"
- "New Zylast article picked up by Sound Medicine at NPR - a potential new tool in the fight against Ebola and disease. Powerful enough for Ebola, safe enough for your family!"

The Facebook page (https://www.facebook.com/ZylastXP/info?tab=page_info) includes a link to a press release entitled Zylast™ Wins USAID "Fighting Ebola Grand Challenge" (<http://www.prnewswire.com/news-releases/zylast-wins-usaid-fighting-ebola-grand-challenge-300009163.html>). Labeling claims found within the press release:

- "The persistence of Zylast is critical in fighting the spread of Ebola. If a healthcare worker comes into contact with an infected person – even one who has not been diagnosed, Zylast provides defense against infection."
- "Zylast kills any Ebola virus that comes into contact with Zylast-treated skin and will persist up to 6 hours after application."

Zylast XP Antiseptic:

- The label for Zylast XP Antiseptic Lotion identifies benzethonium chloride 0.20% as the sole "Active Ingredient" and the "Directions" state "wet hands thoroughly with product and allow to dry without wiping."

Based on their labeling, the Zylast products are "drugs" as section 201(g)(1)(B) of the FD&C Act [21 U.S.C. § 321(g)(1)(B)], because they are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act [21 U.S.C. § 321(g)(1)(C)]

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because they are intended to affect the structure or any function of the body of man. Specifically, these products are intended as topical antiseptics.

Although the Zylast products are labeled as topical antiseptics and include the general use to reduce bacteria and microorganisms on the skin, the products, as demonstrated by the above referenced claims, are also specifically intended for effectiveness against specific serious-disease related pathogens, and for Zylast XP Antiseptic Lotion use as a leave-on product that is not rinsed off.

Zylast products are "new drugs" within the meaning of section 201(p) of the FD&C Act [21 U.S.C. § 321(p)]. As "new drugs," in order to ensure Zylast products are safe and effective for the uses demonstrated by its labeling, the Zylast products as currently formulated and labeled require FDA-approved new drug applications in order to be legally marketed in the United States. Zylast products are not the subjects of approved new drug applications. As new drugs without approved applications, the current marketing of Zylast products violates section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. Introduction of such products into interstate commerce is prohibited under § 301(d) of the FD&C Act [21 U.S.C. § 331(d)].

We note that, in accordance with its announced compliance policy,¹ FDA does not take enforcement action against the marketing of certain over-the-counter (OTC) drugs without approved new drug applications if they are covered by an ongoing OTC monograph rulemaking process. However, as explained in this letter, the Zylast XP products are being marketed for uses that are not part of any ongoing rulemaking.² Specifically, the Zylast XP products deviate from OTC products subject to the OTC monograph rulemaking in two ways: They make pathogen-specific claims that were not, to our knowledge, made at the time the monograph process began and that are not being considered for this type of product. The Zylast XP Antiseptic Lotion is a leave-on product, and no such product has been shown to have existed at the time the OTC monograph process began and no such product is covered by the rulemaking.

Drug products intended for topical antiseptic general use to reduce bacteria and microorganisms on the skin such as the labeled purpose of the Zylast products are being evaluated under the ongoing rulemaking for OTC Topical Antimicrobial Drug Products within FDA's OTC Drug Review. OTC Topical Antimicrobial Drug Products include OTC healthcare antiseptics and OTC consumer antiseptics such as the Zylast products. Tentative final monographs (TFMs) for these products were

¹ FDA's Compliance Policy Guidance 450.200 sets forth our regulatory policy with respect to products being marketed under ongoing OTC monograph rulemaking. We note that, even if the products were covered by the rulemaking, they would warrant FDA enforcement action under that policy because some of their claims are for effectiveness against serious disease related viruses which could preclude obtaining proper medical attention.

² Because so few OTC drugs are the subject of new drug applications (NDAs), in 1972, FDA decided to review all OTC drugs for both safety and efficacy. A review on a drug-by-drug basis would have been impractical since there are an estimated 250,000 OTC drugs on the market. Therefore, FDA announced that the OTC Drug Review would occur on an ingredient and therapeutic-category basis. To accomplish this, FDA convened special review panels. The review procedure for drug products studied by these panels is set forth in 21 CFR Part 330.

Upon review of the recommendations made by the subject panel, FDA publishes a Federal Register announcement containing the Proposed Monograph (i.e., an Advanced Notice of Proposed Rule). After a period of review and comment, the agency then publishes a Tentative Final Monograph (Proposed Rule). Finally, after an additional review and comment period, the agency publishes a Final Monograph (Final Rule). The Final Monograph concerns general recognition of safety and efficacy for the class of OTC drugs that it covers. OTC drugs that deviate from a final monograph are not generally recognized as safe and effective and require approved new drug applications before they can be marketed. But OTC drugs that comply with a Final Monograph do not need approved new drug applications.

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first published in the *Federal Register* in 43 FR 1210 (January 6, 1978) and amended at 56 FR 33644 (July 22, 1991), 59 FR, 31402 (June 17, 1994), and 78 FR 76446 (December 17, 2013). These documents are available on FDA's website at:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm070821.htm>.

Pending a final monograph,³ the agency does not object to the marketing of OTC drugs that meet the formulation and labeling requirements described in the relevant TFM or that are otherwise eligible for inclusion in the OTC Drug Review (*see* 68 FR 75585 at 75590-91, Dec. 31, 2003). However, neither the Zylast products nor similarly formulated and labeled products for the specific intended uses demonstrated by the above claims are eligible for inclusion in the OTC Drug Review or otherwise generally recognized as safe and effective by qualified experts.

In particular, claims to the public, as referenced above, for effectiveness against specific pathogens, and any claims with respect to pathogens such as MRSA, E. coli, norovirus, H1N1, HIV, herpes, influenza, rhinovirus and rotavirus, go beyond merely describing the general intended use of a topical antiseptic as described in the relevant rulemaking. Moreover, such claims are not described in any OTC final monograph, tentative monograph, or any rulemakings being considered under the OTC Drug Review. Also, we are unaware of any evidence that a product so formulated and labeled for such uses was marketed in the United States on or before the inception of the OTC Drug Review.

Moreover, Zylast XP Antiseptic Lotion does not qualify for evaluation under the OTC Drug Review due to its formulation. Although benzethonium chloride at this concentration (0.20%) is covered under FDA's OTC Drug Review for certain uses, it is not covered by the OTC Drug Review when offered as a leave-on/no-rinse healthcare antiseptic cleanser. Furthermore, we are unaware of any evidence of a leave-on/no-rinse healthcare antiseptic cleanser formulated and labeled like Zylast XP Lotion that was marketed in the United States on or before the inception of the OTC Drug Review.

Therefore, as formulated and labeled, the Zylast products are not covered under any OTC monograph or ongoing rulemaking that sets forth conditions for general recognition of safety and effectiveness for such uses. Nor are products intended specifically for effectiveness against specific serious-disease related pathogens, such as MRSA, E. coli, norovirus, H1N1, HIV, herpes, influenza, rhinovirus and rotavirus, being considered under FDA's OTC Drug Review. Additionally, products intended as a non-rinse, leave-on product, such as Zylast XP Antiseptic, are not being considered under FDA's OTC Drug Review. Furthermore, we are not aware of evidence to show that Zylast products as formulated and labeled are generally recognized by qualified experts as safe and effective for their labeled uses.

Additionally, we note claims for the Zylast products include assertions that the products provide six hours of extended efficacy against serious-disease related pathogens such as Ebola, Methicillin-resistant *Staphylococcus aureus* (MRSA), H1N1 flu virus, and norovirus and other microorganisms. Time-specific extended efficacy claims especially when related to serious-disease related pathogens may lead to a false sense of security for the general public by resulting in infrequent hand washing or the substitution of these products for protective gloves and clothing, which are the principal methods

³ Once a final monograph becomes effective, it may be necessary to reformulate and/or relabel such products to conform to its requirements, or, in the alternative, to seek FDA approval of a new drug application (NDA) under section 505 of the FD&C Act [21 U.S.C. § 355].

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for protecting against the spread of diseases caused by pathogenic microorganisms and cross-contamination.

Misbranding Charge

The following labeling claim was included on your website, www.zylastdirect.com:

- “The active ingredient in Zylast, BZT . . . and is considered safe and effective in concentrations of 0.1-0.2% by the FDA.”

FDA has not established nor proposed BZT (benzethonium chloride) to be safe and effective at any concentration when used as a leave-on antiseptic such as Zylast XP Antiseptic Lotion. Thus, this claim is false and misleading, and Zylast XP Antiseptic Lotion is misbranded under section 502(a) of the Act [21 U.S.C. §352(a)]. Additionally, we note that even the rinse-off uses of BZT, which have been evaluated for under the rulemaking, have only been proposed as safe and effective for such uses, so the phrase “is considered” in the above quotation is inaccurate and misleading.

Unsubstantiated Advertising

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. See *POM Wonderful LLC v. FTC*, 777 F.3d 478, 504-05 (D.C. Cir. 2015), *reh'g denied*, 2015 U.S. App. LEXIS 8946 (D.C. Cir. 2015) (en banc); *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 300, 303 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1190, 1202 (N.D. Ga. 2008), *aff'd*, 356 Fed. Appx. 358 (11th Cir. 2009); *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75, 866, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See *In re Daniel Chapter One*, No. 9239, 2009 WL 516000 at *17-19 (F.T.C. Dec. 24, 2009), *aff'd*, 405 Fed. Appx. 505 (D.C. Cir. 2010).

The FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers.

Next Steps

The violations cited in this letter are not intended to be an all-inclusive list of deficiencies regarding your products, nor are the arguments raised here regarding them exhaustive. You are responsible for investigating and determining the causes of these violations and for preventing their recurrence and the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of Federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure

GOV-00014224

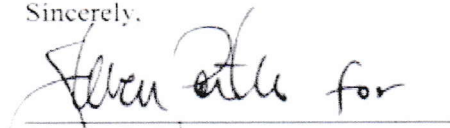
Page 7

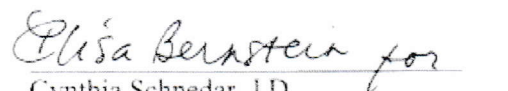
and injunction. Other Federal agencies may take this Warning Letter into account when considering the award of contracts.

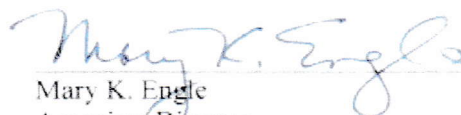
Within 15 working days of receipt of this letter, please notify the applicable FDA and FTC offices specified below in writing of the specific steps that you have taken to correct the referenced violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction. If your firm no longer manufactures or markets any of the Zylast products, your response should indicate this along with the reasons for discontinuation, as well as the date your firm ceased production.

With regard to the advertising claims discussed in this letter, please notify Gregory W. Fortsch of the FTC via electronic mail at gfortsch@ftc.gov within fifteen working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Fortsch at 202-326-3617. With regard to the FDA-related violations described in this letter your reply should be directed to the attention of Mr. Raymond Brullo, Compliance Officer, Food and Drug Administration, Los Angeles District Office, 19701 Fairchild Road, Irvine, CA 92612-2506. If you have questions regarding any issue in this letter, please contact Mr. Brullo at (949) 608-2918 or via electronic mail at raymond.brullo@fda.hhs.gov. You can find guidance and information regarding regulations through links at FDA's website at <http://www.fda.gov/oc/industry>.

Sincerely,


 Alonza E. Cruse
 District Director
 Los Angeles District Office
 U.S. Food and Drug Administration


 Cynthia Schnedar, J.D.
 Office Director
 Office of Compliance
 Center for Drug Evaluation and Research
 U.S. Food and Drug Administration


 Mary K. Engle
 Associate Director
 Division of Advertising Practices
 Federal Trade Commission

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Page 8

Cc:

David M. Mazzer, Branch Chief
California Department of Public Health
Food and Drug Branch
PO Box 997435
1500 Capitol Ave, MS-7602
Sacramento, CA 95899-7413
Attn: FDA correspondence

GOV-00014226

EXHIBIT 7

Message

From: Shah, Anuj [Anuj.Shah@fda.hhs.gov]
Sent: 4/18/2014 7:02:46 PM
To: Harley, Heath [Heath.Harley@fda.hhs.gov]
CC: Shukla, Sudha [Sudha.Shukla@fda.hhs.gov]
Subject: RE: OC ID#13-030: Hyman, Phelps and McNamara, PC - letter dated November 7, 2013

Heath – I concur especially since the claims are only found in the websites and are not the primary focus of the promotion. These products would be good candidates for alternative enforcement strategies such as the Health Fraud’s serious disease alternate enforcement strategy but that is still under development. Thanks.

From: Harley, Heath
Sent: Friday, April 04, 2014 5:48 PM
To: Shah, Anuj
Cc: Shukla, Sudha
Subject: RE: OC ID#13-030: Hyman, Phelps and McNamara, PC - letter dated November 7, 2013

Anuj,

I reviewed the promotional material for **Redacted-DP** and Zylast Antiseptic Lotion and Foaming Hand Soap provided by Hyman, Phelps and McNamara and it appears that the products would be violative based on the claims on promotional material provided (barrier claims, MRSA, time specific protection etc) . However, given CDER’s competing priorities, I do not recommend regulatory action for this product at this time. These product should be catalogued for the possibility of future regulatory action as an OUDLC initiative.

Let me know if you concur with this recommendation and I will close this out with Sudha.

Heath

From: Shah, Anuj
Sent: Monday, November 18, 2013 10:10 AM
To: CDER OUDLC PM TRACK; Harley, Heath
Cc: Shukla, Sudha
Subject: RE: OC ID#13-030: Hyman, Phelps and McNamara, PC - letter dated November 7, 2013

This can go to Heath.

Heath – please make sure Sudha sends an acknowledgement letter and then as time permits evaluate in the context of the broader market to see whether at this time it would be a priority to address these concerns given other priorities. Thanks.

From: CDER OUDLC PM TRACK
Sent: Saturday, November 16, 2013 1:10 PM
To: Harley, Heath
Cc: Shah, Anuj; CDER OUDLC PM TRACK
Subject: FW: OC ID#13-030: Hyman, Phelps and McNamara, PC - letter dated November 7, 2013

Heath – Please let me know if you will assign this. Thanks.



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From: CDER OC IO TRACK**Sent:** Wednesday, November 13, 2013 4:19 PM**To:** CDER OUDLC PM TRACK**Subject:** OC ID#13-030: Hyman, Phelps and McNamara, PC - letter dated November 7, 2013

The following request is on the IO OC incoming mail log track sheet as IO OC INC#13-030.

When OUDLC responds to the request, please copy the CDER OC IO track mailbox, and we'll close out the request on the track sheet.

Thanks,

Margaret

From: Sue Ling, Marlene F**Sent:** Tuesday, November 12, 2013 4:20 PM**To:** CDER-OC-IO Incoming; CDER Compliance Mailbox**Subject:** Hyman, Phelps and McNamara, PC - letter dated November 7, 2013

<< File: Hyman, Phelps & McNamara, PC - letter dtd 11-7-13.pdf >>

Please review and process the attached letter as deemed appropriate.

Thanks,

Marlene

EXHIBIT 8

42 captures

16 Dec 2014 - 23 Jul 2019

**USAID**
FROM THE AMERICAN PEOPLE

USAID LEADERSHIP

[HOME](#) » [NEWS & INFORMATION](#) » [PRESS RELEASES](#) » UNITED STATES ANNOUNCES RESULTS OF GRAND CHALLENGE TO FIGHT EBOLA

UNITED STATES ANNOUNCES RESULTS OF GRAND CHALLENGE TO FIGHT EBOLA

Innovative personal protective equipment solutions selected for funding, testing and deployment

For Immediate Release

Friday, December 12, 2014

USAID Press Office

Telephone: +1.202.712.4320 | Email: USAIDPressOfficers@usaid.gov | Twitter: @USAIDPress

WASHINGTON, D.C. – The U.S. Agency for International Development (USAID) announced today the first nominees for awards in the *Fighting Ebola: a Grand Challenge for Development*. Following a rigorous selection process, these innovators have been identified for the solutions they presented to increase the protection and comfort of healthcare workers battling Ebola.

"The *Fighting Ebola* Grand Challenge embodies our new model of development – bringing together the world's brightest minds to solve our biggest global challenges," said USAID Administrator Rajiv Shah, who will share a prototype of one of the selected designs at the White House. "By working together with our partners from government, business, and civil society, we are creating innovations that will not only help West Africa's most vulnerable communities beat the Ebola epidemic, but also break the cycle of extreme poverty."

Led by USAID, the Challenge launched in early October and sourced new, practical solutions in partnership with the White House Office of Science and Technology Policy, the Centers for Disease Control and Prevention, and the Department of Defense. In just two months, innovators from around the world submitted over 1,500 ideas focused on helping frontline health care workers to provide better, more timely care and to contain this devastating virus. After hearing pitches from top innovators, U.S. Government experts and international partners selected the most promising ideas through a rapid, rigorous review process. This first round of awards focuses on improving the safety and comfort of the personal protective equipment (PPE) worn by healthcare workers and alleviating the heat stress it can cause in the hot, humid climates of West Africa.

Three innovations will receive financial and/or other support and undergo intensive testing to ensure readiness for production and field deployment:

- **Johns Hopkins University's Center for Bioengineering Innovation & Design (CBID) & Jhpiego**
Healthcare worker suit redesigned for quicker and safer doffing/removal with integrated cooling features utilizing technology from Johns Hopkins University
- **Aquarius GEP LLC and Innovative BioDefense**
Antiseptic that, when applied to skin, provides up to six hours of pathogen protection and serves as an anti-microbial barrier to viral transmission for health care workers
- **SPR Advanced Technologies, Inc.**
Long-lasting, spray-on barrier that kills and repels microbes with electro-static fields to prevent surface contamination and allow for more breathable PPE materials

USAID is also partnering with The Global Good Fund/Intellectual Ventures to rapidly evaluate several cooling solutions, including:

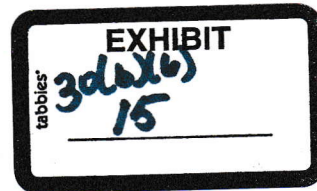
- **Phase-Change Material Cooling Solutions**
Off-the-shelf, rapidly deployable cooling garments currently used by military that can be worn underneath existing PPE
- **Qore Performance, Inc. (Arterial Cooling Base Layer System)**
An innovative base layer cooling solution from a sports-wear company that cools the body by cooling the blood at pulse points

Through a whole-of-government approach, USAID and our U.S. Government partners are mounting an aggressive effort to fight the Ebola outbreak in West Africa. Our goal is to enable the most effective international response possible, using our government-wide capabilities to fight the epidemic on a regional basis. The initial round of award nominations under the *Fighting Ebola* Grand Challenge focused on solutions to improve the protection and comfort of healthcare workers; additional award nominations for other innovations will be announced in the coming weeks.

The U.S. Agency for International Development's Grand Challenge for Development initiative crowd-sources solutions to solve clearly-defined problem sets, engaging the world in a quest to discover, incubate, test, and accelerate innovative solutions that have the potential to solve the world's greatest development challenges.

For updates on the Fighting Ebola Grand Challenge and to follow new opportunities to participate, subscribe here:

<http://www.usaid.gov/grandchallenges/ebola#mail>.



8/30/2019

United States Announces Results of Grand Challenge to Fight Ebola | Press Release | U.S. Agency for International Development

Page ID #: 2672

http://www.usaid.gov/news-information/press-releases/dec-12-2014-united-states-announces-results-grand-challenge-fight-ebola Go NOV DEC FEB

42 captures 16 2013 2014 2016 About this capture

16 Dec 2014 - 23 Jul 2019

USAID Airlifts Medical Supplies to West Africa for Ebola Response

UPDATED: USAID Assistant Administrator Ariel Pablos-Mendez Travels to Liberia

First U.S.-Constructed Ebola Treatment Unit Set to Open in Liberia

Last updated: December 12, 2014

SHARE THIS PAGE

EXHIBIT 9

Message

From: Smith, Tina (Walther) [/O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=WALTHER]
Sent: 3/19/2015 6:55:08 PM
To: Winestock, Karen [Karen.Winestock@fda.hhs.gov]
Subject: RE: FW: Questions on Ebola Diagnostics

Thanks!

Tina

Tina (Walther) Smith | Lieutenant Commander, USPHS | Team Leader, OTC Team I | Over-The-Counter Drugs Branch | Division of Non-Prescription Drugs & Health Fraud | Office of Unapproved Drugs and Labeling Compliance | FDA/CDER | Phone: 301-796-5086

From: Winestock, Karen
Sent: Thursday, March 19, 2015 2:55 PM
To: Smith, Tina (Walther)
Subject: FW: FW: Questions on Ebola Diagnostics

Attached is the most comprehensive group of messages regarding the USAID issue.

From: Winestock, Karen
Sent: Monday, March 02, 2015 4:06 PM
To: 'Marissa Leffler'
Cc: Wendy Taylor; Kosko, Robert; Chu, May
Subject: RE: FW: Questions on Ebola Diagnostics

Hello Ms. Leffler,

We are unable to answer most of your questions because the sponsor will need to submit a PreIND that includes more information than you have provided. Our preliminary response to bulleted item 1 is provided below, but it might change after we have reviewed the information the sponsor has obtained to date.

Karen

From: Marissa Leffler [<mailto:mleffler@usaid.gov>]
Sent: Thursday, February 19, 2015 11:50 AM
To: Winestock, Karen
Cc: Wendy Taylor; Kosko, Robert; Chu, May
Subject: Re: FW: Questions on Ebola Diagnostics

Thank you, Karen. Please find our questions below. We very much appreciate your guidance.

- What Ebola-specific testing, if any, is considered necessary for an antiseptic product that would be recommended for use by health care workers treating Ebola-infected patients? Is it sufficient for the product to have been tested on a non-enveloped virus?
- Some virus groups are highly resistant to antiseptics. Therefore, this reviewer does not agree with the concept of a broad "antiviral" indication and has recommended in the past that antiseptics be evaluated in a clinical trial. Nonclinical data consistent with product use could be used to support an IND to study the antiseptic. Specifically, that would involve studies assessing inactivation of a filovirus. However, the sponsor would need to develop an alternative to the fingerpad method.
- If Ebola-specific testing is not necessary, might it still be recommended?
- Is an antiseptic product required to be GRASE? What kind of testing is required to establish that standard?

- Does the FDA do any verification of company claims of meeting the tentative final monograph designation/standard?

Best regards,
Wendy and Marissa

On Tue, Feb 17, 2015 at 4:49 PM, Winestock, Karen <Karen.Winestock@fda.hhs.gov> wrote:
Wendy,

Please send your questions.

Karen

From: Wendy Taylor [mailto:wetaylor@usaid.gov]
Sent: Friday, February 13, 2015 8:48 PM
To: Winestock, Karen
Cc: Marissa Leffler; Kosko, Robert; Chu, May

Subject: Re: FW: Questions on Ebola Diagnostics

Karen - Instead of asking specifically about a product, can we ask a few general questions about testing against EVD? I'm sure you've been engaged in some of these discussions in light of the current outbreak. Some general guidance would be very helpful.

Thanks,
Wendy

Director
Center for Accelerating Innovation and Impact
USAID

On Fri, Feb 13, 2015 at 5:04 PM, Winestock, Karen <Karen.Winestock@fda.hhs.gov> wrote:
Good afternoon,

FDA cannot provide regulatory guidance to USAID about a product for which you are not the sponsor. If the sponsor decides to contact the FDA for assistance, USAID can specify in the contract that you want to be included in meetings or that the sponsor has to provide USAID with any FDA correspondence.

Best regards,

Karen Winestock
Chief, Project Management Staff
Division of Antiviral Products

Center for Drug Evaluation and Research

301-796-0834 or 301-796-1500

From: Marissa Leffler [mailto:mleffler@usaid.gov]

Sent: Thursday, February 12, 2015 2:53 PM

To: Winestock, Karen

Cc: Wendy Taylor; Kosko, Robert

Subject: Re: FW: Questions on Ebola Diagnostics

Dear Karen,

I wanted to follow up to see if you might have any thoughts on the proposed EVD testing for Zylast as outlined below. Might you or someone on your staff have a few minutes to discuss over the phone?

Please let me know.

Many thanks,

Marissa

On Sat, Feb 7, 2015 at 12:48 PM, Marissa Leffler <mleffler@usaid.gov> wrote:

Thanks, Karen. We are not the inventors/manufacturers of the antiseptic product. Wendy and I work at USAID and are considering providing funding to the company that makes the product to support testing against Ebola. The use-case is for application to the skin by health care workers prior to donning PPE. The product (Zylast) lasts for 6 hours, according to studies conducted by the company. We are contemplating funding additional persistence testing under conditions representative of the West Africa environment (i.e., heavy sweating) to ensure that these conditions do not substantially alter the product's persistence, as this is a key benefit. We also are contemplating funding testing the product on EVD. Someone who could provide insight into whether this second component of testing is necessary and/or recommended given the testing they already have conducted would be very helpful to us at this stage. The product already meets the FDA TFM standards.

Many thanks in advance for your guidance.

Best,

Marissa

On Fri, Feb 6, 2015 at 5:44 PM, Winestock, Karen <Karen.Winestock@fda.hhs.gov> wrote:

Good afternoon,

I am acknowledging receipt of your message. I am unable to provide any quick feedback as I know nothing about your drug. However, I would think in vivo or cell culture data that supports your product is effective against the Ebola virus would be a good starting point.

Please submit a request for PreIND consultation with a list of question you want the Division to address.

The link to the Division of Antiviral Products' PreIND Consultation Program is attached.

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/ucm077776.htm>

Best Regards,

Karen Winestock
Chief, Project Management Staff
Division of Antiviral Products
Center for Drug Evaluation and Research
301-796-0834 or 301-796-1500

From: Wendy Taylor [mailto:wetaylor@usaid.gov]
Sent: Friday, February 06, 2015 2:01 PM
To: Hojvat, Sally A
Cc: Gaffey, Claudia M.; Winestock, Karen; Leffler, Marissa (GH/PRH/PEC)
Subject: Re: FW: Questions on Ebola Diagnostics

Thanks so much Sally. I'm also adding in Marissa who is handling this particular innovation. She had been connected by someone else to Allison Kumar although I don't believe they've connected yet.

The product is a long-lasting antiseptic, Zylast, that is currently on the market and meets the Tentative Final Monograph. We are interested in it for use with Ebola and are trying to confirm what additional testing may be necessary.

Wendy

On Fri, Feb 6, 2015 at 1:18 PM, Hojvat, Sally A <Sally.Hojvat@fda.hhs.gov> wrote:
Hi Wendy,

The Center /Division at FDA that reviews antiseptics may depend on whether the product you are referring to is a specific antiseptic for ebola (CDER, Division of Antiviral Products (DAVP) or, a more general product (CDER, Division of Nonprescription Clinical Evaluation (DNCE).

The Supervisory Project Manager for DAVP is Karen Winestock ([301-796-0834](tel:301-796-0834)), I would try there first. I have copied her on this e mail.

We tried calling her this morning but could not reach her.

Regards,

Sally

FYI, Peyton is currently on a detail to CBER for 4 months so I would appreciate if you could send any questions directly to myself in the interim.

Sally A. Hojvat, Ph.D., M.Sc
Director
Division of Microbiology Devices
Office of In-Vitro Diagnostics and Radiological Health
CDRH/FDA
10903 New Hampshire Avenue
White Oak 66, Room 5524
Silver Spring
MD 20993
Tel: [301-796-5455](tel:301-796-5455)

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From: Wendy Taylor [<mailto:wetaylor@usaid.gov>]
Sent: Wednesday, February 04, 2015 3:05 PM
To: Hobson, John (Peyton); Leffler, Marissa (GH/PRH/PEC)
Subject: Re: Questions on Ebola Diagnostics

Can you help us find the right person at FDA who reviews antiseptics -- particularly with an eye to Ebola? We have a few products that we're funding and would like to get some quick advice.

Many thanks.

Wendy

EXHIBIT 10

~~HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY~~

LAW OFFICES

HYMAN, PHELPS & MCNAMARA, P.C.

700 THIRTEENTH STREET N.W.

SUITE 1200

PAUL M. HYMAN

WASHINGTON, D.C. 20005-5829

(202) 737-5800

FACS/MILE

(202) 737-9329

www.hpm.com

Direct Dial (202) 737-4281
PHyman@hpm.com

December 23, 2014

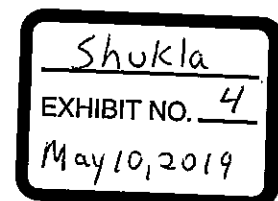
BY FEDERAL EXPRESS AND E-MAIL

Ms. Cynthia A. Schnedar
 Director, Office of Compliance
 Center for Drug Evaluation and Research
 Food and Drug Administration
 White Oak Office Building 51
 10903 New Hampshire Avenue, Room 5270
 Silver Spring, Maryland 20993-0002

Dear Ms. Schnedar:

In a November 7, 2013 letter to Howard Sklamberg, then Director of the Office of Compliance, I called the attention of your office to flagrantly violative claims for topical over-the-counter (OTC) antimicrobial products marketed by three companies (copy attached). I pointed out that those labeling and advertising claims rendered the products misbranded and unapproved new drugs. Although a representative of the Office of Unapproved Drugs and Labeling Compliance responded by e-mail and subsequent telephone conference, to my knowledge the agency has taken no regulatory action against any of those companies.

One company cited in that letter, Innovative Biodefense, Inc., not only has blatantly continued to make the same violative claims for its Zylast Antiseptic products, but has now added Ebola claims to its promotional materials. See <http://www.prnewswire.com/news-releases/zylast-wins-usaid-fighting-ebola-grand-challenge-300009163.html> (copy attached). See also attached "Zylast - Ebola Technical Bulletin for Healthcare Professionals." As with the previously noted long-lasting barrier type persistence claims, anti-viral claims, and implied combination therapy claims, Ebola prevention claims are not included in the Tentative Final Monograph for Healthcare Antiseptic Drug Products. 59 Fed. Reg. 31,402 (June 17, 1994) (TFM), and further render the products misbranded and unapproved new drugs.



FDACDER0000180

GOV-00000628

Ms. Cynthia A. Schnedar
December 23, 2014
Page 2

HYMAN, PHELPS & MCNAMARA, P.C.

The company actively promotes the use of its product for Ebola prevention on its web site and Facebook pages as well as in the above-referenced December 12, 2014 press release. While the selection of the product by U.S. Aid may be legitimate, the promotion of the product for use against Ebola, in the U.S. or elsewhere, makes it an unapproved new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act (FDC Act). Moreover, connecting the purported use of the product for Ebola to the use of the product for flu and other viral diseases is particularly egregious. See, e.g., Facebook page https://www.facebook.com/ZylastXP/timeline?ref=page_internal, which states: "With Zylast winning the National Fighting Ebola Grand Challenge, we want to offer the same protection to all of our customers over the flu season. Head to ZylastDirect.com and use the coupon code FightingEbola to save 10% on Zylast. Makes a great stocking stuffer!"

The company's misleading exploitation of the Ebola designation is entirely consistent with its flagrant disregard for the limits on the uses of OTC topical healthcare antiseptic products under the TFM. A cursory review of the company's web pages and Facebook site discloses that the company makes virtually every claim that FDA has objected to for this class of products. Examples include:

<http://www.zylastdirect.com/> (left hand side of page, about halfway down)
"Zylast kills influenza, "the flu" and killed 99.99% of the H1N1 strain in 15 seconds!"
"It is also 100 times more effective than alcohol-based sanitizers against the stomach flu."
"Zylast kills more than 99% of Rhinovirus, the highly contagious "common cold" on contact!"

<http://www.zylastdirect.com/at-home/>
"Because Zylast not only kills germs to include viruses and drug-resistant bacteria, but is also persistent for 6 hours, you and your loved ones will continue to be protected"

<http://www.zylastdirect.com/school/>
"And Zylast kills more than just transient bacteria. It is effective against a broad spectrum of germs to include the viruses responsible for the colds and flus"
"There are three primary reasons for a reduction in illness with the Zylast Lotion. First, the Zylast products are persistent for six hours so children are protected beyond the 15-second lifespan of an alcohol sanitizer. Second, the Zylast Lotion is effective against pathogens like the Norovirus, rotavirus, and the common cold – some of the most prevalent diseases among children, and germs against which

Ms. Cynthia A. Schnedar
December 23, 2014
Page 3

HYMAN, PHELPS & MCNAMARA, P.C.

alcohol sanitizers are relatively ineffective. Finally, the product is water-based and moisturizes the hands, so children and staff actually like using it which greatly improves compliance."

<http://www.zylastdirect.com/work/>

Zylast Eliminates:

Norovirus (The Stomach Flu) 99.97%

E. coli 99%

MRSA & VRE 99%

Cold & Flu Viruses 99%

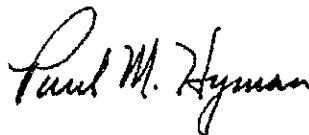
<http://www.zylastdirect.com/travel/#> (Dual active ingredient?)

"The Zylast products are specifically designed to bond with the skin and provide persistent protection against transient germs. Using the same in-vitro skin model, the active ingredients in the Zylast Antiseptic were studied and compared against leading market products. The product with **the combination of ethanol and BZT** significantly outperformed every product on the market against transient bacteria, both gram-positive and gram-negative."

Given the scope, extent and flagrancy of these violative claims, FDA should take quick and decisive enforcement action to halt their continued dissemination in order to protect the public and the integrity of the drug regulatory process.

Because this matter involves unapproved claims for preventing Ebola, I am sending a copy to the Federal Trade Commission, which I understand has worked with FDA recently to protect consumers from false or misleading claims for Ebola products. This appears to be a prime example of a firm that merits such combined attention.

Sincerely,



Paul M. Hyman

PMH/eam

Attachments

cc: Richard L. Cleland
Federal Trade Commission

FDACDER0000182

GOV-00000630

EXHIBIT 11

Message

From: Shah, Anuj [/O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SHAHA]
Sent: 12/24/2014 5:41:29 PM
To: Auchincloss, Kalah [Kalah.Auchincloss@fda.hhs.gov]; Smith, Tina (Walther) [Tina.Walther@fda.hhs.gov]; Miller, Elizabeth [Elizabeth.Miller@fda.hhs.gov]
CC: Kim, In [In.Kim@fda.hhs.gov]; Pace, John (Brad) [John.Pace@fda.hhs.gov]; Harley, Heath [Heath.Harley@fda.hhs.gov]; Shukla, Sudha [Sudha.Shukla@fda.hhs.gov]; Rowley, Ayana [Ayana.Rowley@fda.hhs.gov]
Subject: Re: Ebola Claims for an OTC Drug

I concur

From: Auchincloss, Kalah
Sent: Wednesday, December 24, 2014 10:39 AM
To: Smith, Tina (Walther); Miller, Elizabeth; Shah, Anuj
Cc: Kim, In; Pace, John (Brad); Harley, Heath; Shukla, Sudha; Rowley, Ayana
Subject: Re: Ebola Claims for an OTC Drug

No acknowledgment has been sent, so we should do that. If Anuj and Elizabeth agree, I support the WLs. Thanks!

From: Smith, Tina (Walther)
Sent: Wednesday, December 24, 2014 09:13 AM
To: Miller, Elizabeth; Shah, Anuj; Auchincloss, Kalah
Cc: Kim, In; Pace, John (Brad); Harley, Heath; Shukla, Sudha; Rowley, Ayana
Subject: RE: Ebola Claims for an OTC Drug

Hi,

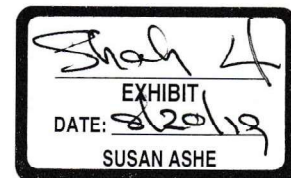
Do we know if the office has sent an acknowledgement response to Hyman's December 23rd letter?

I have reviewed the websites of the three referenced products within the letter and I am most concerned about products 1 and 2 listed below. I would like to issue warning letters against these two firms if the group concurs.

In: can you please send us the template you used for Fraud Ebola letters?

Thanks,

Tina



Preliminary Review:

1. Innovative Biodefense, Inc.. (Zylast Antiseptic products): <http://www.zylastdirect.com/> and <http://www.zylast.com/Default.aspx>; disease specific claims including **Ebola (claims the US announced them as one of the winners of a challenge to fight Ebola)**, Rhinovirus (common cold), Rotavirus (diarrhea, especially in children), H1N1, Influenzae, HIV, and Herpes viruses, persistence claims – can buy products directly from the website.

DP, N-R

DP, N-R

From: Miller, Elizabeth
Sent: Tuesday, December 23, 2014 6:06 PM
To: Smith, Tina (Walther); Rowley, Ayana
Cc: Kim, In; Shah, Anuj; Pace, John (Brad); Auchincloss, Kalah
Subject: FW: Ebola Claims for an OTC Drug

Tina and Ayana, please evaluate. In can likely offer input as she worked on the Fraud Ebola letters.

From: Auchincloss, Kalah
Sent: Tuesday, December 23, 2014 5:04 PM
To: Miller, Elizabeth; Shah, Anuj
Subject: FW: Ebola Claims for an OTC Drug

FYI

From: Schnedar, Cynthia
Sent: Tuesday, December 23, 2014 5:00 PM
To: Auchincloss, Kalah
Cc: Bernstein, Ilisa; Levy, Michael (CDER); Lou, Allen; Sue Ling, Marlene F
Subject: FW: Ebola Claims for an OTC Drug

Kalah,

Would this fall within OUDLC's jurisdiction?

From: Paul M. Hyman [<mailto:PHYman@hpm.com>]
Sent: Tuesday, December 23, 2014 11:37 AM
To: Schnedar, Cynthia
Subject: Ebola Claims for an OTC Drug

Dear Ms. Schnedar:

Attached is a letter describing violative labeling and promotional claims for an OTC topical antimicrobial drug product relating to prevention of Ebola. The manufacturer further cites the use in Ebola as evidence of the drug's effectiveness for other viruses and uses not permitted by the pending Healthcare Antiseptic Tentative Final Monograph. FDA needs to take prompt, effective action against that misbranded and unapproved new drug in order to protect the public health.

Sincerely,

Paul M. Hyman
Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-4281, direct dial
(202) 737-9329, fax
phyman@hpm.com

www.hpm.com

Visit the HPM blog at: www.fdalawblog.net

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delete the e-mail and any attachments and notify us immediately.

EXHIBIT 12



USAID
FROM THE AMERICAN PEOPLE

April 20, 2015

Aquarius Global Energy Partners, LLC
Attn: Mr. Dan Putalik
117 East 71st Street #4A
New York, NY 10021

putalik@aquariusgep.com

Reference: AID-OAA-F-15-00016, Aquarius Global Energy Partners, LLC
Subject: **Rescinding of Award Pre-Authorization Letter to Incur Cost Notice issued March 18, 2015**

Dear Sir/Madam,

The US Agency for International Development (USAID) issued a Pre-Authorization letter to incur expenses to the potential award for "Zylast, Preventing the Spread of Ebola" of an amount not exceeding \$75,000. This authorization was provided with the mutual understanding that your organization will proceed at its own risk and in no way obligates the United States Government or USAID to reimburse for any reason expenses incurred in the event the award is not made, of which your firm accepted on March 18, 2015.

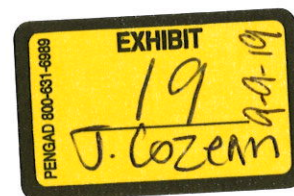
The Pre-Authorization mentioned above is hereby rescinded until further notice by USAID.

USAID requires that your firm discontinues incurring any expenses or associated activities in relation to this potential award.

Sincerely,

Stephanie Fugate
Agreement Officer, M/OAA/SIDP/B

CC: Marissa Leffler (AOR)



HIGHLY CONFIDENTIAL - ATTORNEY'S EYES ONLY

IBD003162

EXHIBIT 13

Message

From: Harley, Heath [/O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=HHARLEY]
Sent: 11/30/2015 9:38:31 PM
To: Smith, Tina (Walther) [Tina.Walther@fda.hhs.gov]
Subject: RE: USAID
Attachments: Zylast/Innovative Biodefense

Hello Tina,

I contacted Wendy Taylor of USAID to confirm that question Sept 9th (See attached email) but I did not receive a response.

I recall we had contact with USAID by email or phone (I'll have to check) saying that they would revoke the funding but I don't know if we received confirmation from USAID.

I will also go through the Biodefense correspondence they may have indicated in their correspondence that they lost funding from USAID.

Heath

From: Smith, Tina (Walther)
Sent: Monday, November 30, 2015 4:27 PM
To: Harley, Heath
Subject: RE: USAID

Hi Heath,

Did you get a chance to reach out to USAID? If I remember correctly, they sent out the letter revoking the funding.

Tina

From: Tave, Steven
Sent: Monday, November 30, 2015 4:22 PM
To: Miller, Elizabeth; Smith, Tina (Walther)
Cc: Anderson, Kathleen R
Subject: Fw: USAID

Can you please let me know (or answer Matt)? Thanks!

From: Brancazio, Matthew (FDA) <Matthew.Brancazio@fda.hhs.gov>
Sent: Monday, November 30, 2015 4:11 PM
To: Tave, Steven; Anderson, Kathleen R
Subject: USAID

Cynthia asked me to find out if USAID removed the award presented to Innovative BioDefense from their website or revoked the award previously given?

Thanks!

Matt Brancazio, Pharm.D., MBA
CDR, U.S. Public Health Service Commissioned Corps
Special Assistant - Office Director

Office of Compliance/Immediate Office
CDER/FDA

(301) 796-5343 (office)

(301) 847-8747 (fax)

matthew.brancazio@fda.hhs.gov

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EXHIBIT 15

Message

From: Paul M. Hyman [PHyman@hpm.com]
Sent: 10/1/2015 8:17:11 PM
To: Brullo, Raymond W. [Raymond.Brullo@fda.hhs.gov]; 'gfortsch@ftc.gov' [gfortsch@ftc.gov]
CC: Schnedar, Cynthia [Cynthia.Schnedar@fda.hhs.gov]; Cruse, Alonza [Alonza.Cruse@fda.hhs.gov]
Subject: FW: Letter to FDA & FTC
Attachments: Hyman to FDA FTC re Innovative Biodefense Zylast 1 Oct 2015 (00152893).pdf

Gentlemen:

Attached is a letter calling your attention to the current labeling and advertising for Zylast antiseptic drug products, which continue to make the same violative claims for the products that were challenged in your June 30, 2015 warning letter to Innovative Biodefense Inc. The company seems to believe that the claims are allowed if they are designated as "educational" in nature and intent.

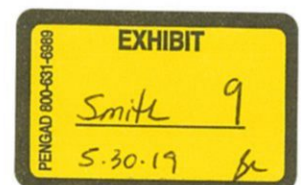
Whether attributable to naiveté or otherwise, this conduct would appear to require prompt and decisive action by your agencies.

Sincerely,
Paul M. Hyman

Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-4281, direct dial
(202) 737-9329, fax
phyman@hpm.com
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LAW OFFICES
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PAUL M. HYMAN

700 THIRTEENTH STREET, N.W.
SUITE 1200

WASHINGTON, D.C. 20005-5929

(202) 737-5800

FACSIMILE
(202) 737-9329

www.hpm.com

Direct Dial (202) 737-4281
PHyman@hpm.com

October 1, 2015

BY E-MAIL

Mr. Raymond Brullo
Compliance Officer
Food and Drug Administration
Los Angeles District Office
19701 Fairchild Road
Irvine, CA 92612-2506
raymond.brullo@fda.hhs.gov

Gregory W. Fortsch, J.D.
Assistant Director
Federal Trade Commission
Bureau of Consumer Protection
600 Pennsylvania Avenue, NW
Washington, DC 20580
gfortsch@ftc.gov

Re: Innovative Biodefense Inc.

Dear Messrs. Brullo and Fortsch:

As you may be aware, our firm previously called your offices' attention to labeling and advertising violations by Innovative Biodefense Inc. (IBD) with respect to its Zylast antiseptic drug product line. Your agencies clearly agreed with the concerns we raised and, on June 30, 2015, issued a warning letter to IBD demanding prompt correction of those violations. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm453717.htm>.

However, we have been informed that, rather than removing the violative claims, the company has continued to make most of them in promotional labeling and advertising, accompanied by the incredible disclaimer that they are being presented "for educational purposes only." For example, each page of the company's website contains the following disclaimer:

The information on this website is for educational purposes only. Zylast does not make, and the FDA does not allow from any manufacturer, claims of efficacy against specific bacteria or viruses. For more information, see the Terms and Conditions.

<http://www.zylast.com/> (last accessed on October 1, 2015). The "Terms and Conditions" repeat the disclaimer.

Re: Innovative Biodefense Inc.

HYMAN, PHELPS & MCNAMARA, P.C.

October 1, 2015

Page 2

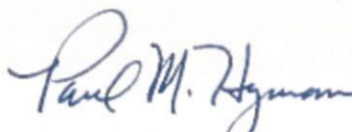
That disclaimer purports to apply to – and excuse – unapproved new drug and misbranded labeling and unsubstantiated advertising claims for the product's use against viruses, MRSA, E. coli, Norovirus, stomach flu, influenza, and for the product's persistence as a leave-on product. The implied claim for Ebola also is still on the site.

Further evidence of the continued use of the violative claims can be seen in the attached marketing piece that was obtained at a trade show two weeks ago. The document touts the "persistent" effect of the product on Norovirus, includes the implied Ebola claim, and again asserts: "This information is for educational purposes only. Zylast does not make, and the FDA does not approve, claims of effectiveness against specific bacteria or viruses."

It is inconceivable that FDA or the FTC would accept this laughable response as addressing the agencies' concerns in the warning letter. In essence, IBD is asserting the right to continue to make objectionable violative claims as long as they are accompanied by the disclaimer that they are "educational" and not allowed by FDA. Imagine how welcome this policy would be to many in the regulated community.

In sum, it is clear that the Zylast products are still being promoted with claims that violate the law and your agencies' policies, which were explicitly addressed in the warning letter. Under those circumstances, FDA and the FTC should take prompt and decisive action to bring these violations to an end.

Sincerely,



Paul M. Hyman

PMH/eam
Attachment

cc: Cynthia Schnedar, J.D., Director, FDA Office of Compliance
Cynthia.Schnedar@fda.hhs.gov
Alonza Cruse, District Director, FDA Los Angeles District Office
Alonza.Cruse@fda.hhs.gov
Mary Engle, Associate Director, FTC Div. of Advertising Practices

Attachment

A Revolution in Hand Hygiene

	Alcohol Sanitizer	Zylast
Rapid Germ Kill	✓	✓
Persistent		✓
Shown to Kill > 99% of Norovirus ²		✓
Shown to improve overall hand feel of HCWs by 46% in hospitals ¹		✓
Winner Fighting Ebola Grand Challenge*		✓

Standard alcohol sanitizers only work until they evaporate (about 15 seconds) and then hands can immediately become recontaminated.

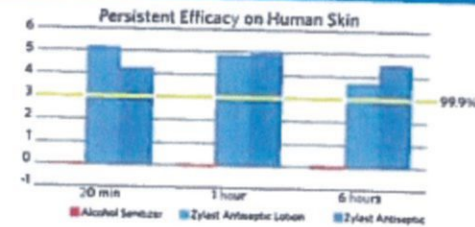
Zylast is different, offering both immediate kill but also persistence, and is the most advanced hand sanitizer ever developed. See the back for more details, or visit us at www.Zylast.com.



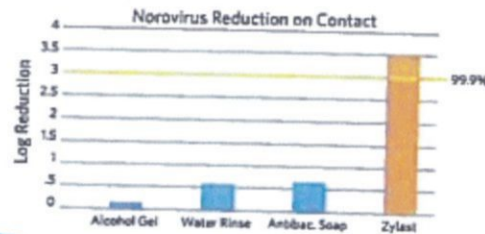
*The Fighting Ebola Grand Challenge was awarded by experts from the CDC, USAID, White House Science and Technology Office, and the Dept of Defense to "groundbreaking innovations" in the field. Zylast was one of three initial winners out of 1500 applicants, and the only hand hygiene product.

A Revolution in Hand Hygiene

Persistent: Zylast is persistent for six hours; alcohol sanitizers only work until they evaporate, about 15 seconds. In testing on human skin, Zylast killed more than 99.9% of germs that came into contact with the skin, even 6 hours after application!¹



Zylast was proven to be more than 100 times more effective than alcohol alone against Norovirus, the cause of the stomach flu and one of the most difficult viruses to kill.²



1. BioScience Laboratories, In-vivo Cup Scrub Testing for Persistence against E. coli, 2014.

2. Czerwinski SE, Cozean J. An evaluation of a Hand Sanitizer Product to Reduce Norovirus Cross Infection, British Global Travel Health Association Journal, 20: 42-46, 2012.

3. Cozean et al., Unpublished clinical trial in hospital, 2014.

This information is for educational purposes only. Zylast does not make, and the FDA does not approve, claims of effectiveness against specific bacteria or viruses.

EXHIBIT 16

Message

From: Smith, Tina (Walther) [Tina.Walther@fda.hhs.gov]
Sent: 2/20/2015 1:50:17 PM
To: Harley, Heath [Heath.Harley@fda.hhs.gov]
Subject: Zylast FW: Message from Unknown sender (2027374281)
Attachments: VoiceMessage.wav

Hi Heath,

Paul Hyman is following up on his complaint about Zylast. I know that you have a lot on your plate right now but we are going to need to move forward with Zylast. If you don't mind, could you please obtain a contact for USAid by early next week and then you, Anuj, and I can discuss the next steps (contacting USAid and maybe calling Paul Hyman).

Thanks,

Tina

From: Cisco Unity Connection Messaging System [mailto:unityconnection@fdsla04029.fda.hhs.gov]
Sent: Thursday, February 19, 2015 2:54 PM
To: shuklasu@fdsla04029.fda.hhs.gov
Subject: Message from Unknown sender (2027374281)



VoiceMessage.w...



GOV-00005755
GOV-00005755.00001

Exhibit

Original is an audio recording

EXHIBIT 18

Message

From: Smith, Tina (Walther) [/O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=WALTHER]
Sent: 3/13/2015 6:32:05 PM
To: Shukla, Sudha [Sudha.Shukla@fda.hhs.gov]; Harley, Heath [Heath.Harley@fda.hhs.gov]
CC: Shah, Anuj [Anuj.Shah@fda.hhs.gov]
Subject: RE: Ebola Claims for an OTC Drug

Thanks for making us aware of this.

Tina

From: Shukla, Sudha
Sent: Friday, March 13, 2015 2:13 PM
To: Harley, Heath; Smith, Tina (Walther)
Cc: Shah, Anuj
Subject: FW: Ebola Claims for an OTC Drug

Please see the below from Mr. Hyman regarding Zylast.

Sudha

From: Paul M. Hyman [mailto:PHyman@hpm.com]
Sent: Friday, March 13, 2015 1:32 PM
To: Shukla, Sudha
Subject: RE: Ebola Claims for an OTC Drug

Dear Dr. Shukla:

This is a much delayed follow-up to our call earlier this month concerning the promotion of Zylast™ for use to prevent Ebola. The following are recent articles published after our complaint letter that discuss that use. They are certain to have been based on information provided by the manufacturer.

<http://kios.org/post/it-kills-germs-six-hours-can-it-wipe-out-ebola>

<http://www.europeancleaningjournal.com/magazine/articles/latest-news/new-hand-sanitiser-could-help-protect-against-ebola>

<http://www.womansday.com/health-fitness/womens-health/a48262/stop-ebola-with-hand-sanitizer/>

As I mentioned, the product also continues to be actively promoted for other uses that FDA regards as appropriate only for approved new drugs, such as norovirus and MRSA. <http://www.zylast.com/TheScience.aspx>. In addition, the product is marketed with claims for 6 hours of "persistent protection," which FDA has held not to be an acceptable claim under the ongoing OTC review of topical healthcare antiseptic drug products.

These actions warrant prompt and decisive regulatory action.

Sincerely,
Paul M. Hyman

Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-4281, direct dial
(202) 737-9329, fax
phyman@hpm.com



www.hpm.com

Visit the HPM blog at: www.fdalawblog.net

From: Shukla, Sudha [<mailto:Sudha.Shukla@fda.hhs.gov>]

Sent: Wednesday, December 24, 2014 11:41 AM

To: Paul M. Hyman

Subject: RE: Ebola Claims for an OTC Drug

Dear Mr. Hyman,

This is in acknowledgement of your letter dated December 23, 2014 addressed to Cynthia Schnedar, Director, Office of Compliance, Food and Drug Administration. In your letter you expressed belief that the labeling and promotion of Zylast Antiseptic Products by Innovative Biodefense Inc., does not conform to the OTC topical healthcare antiseptic products under the TFM, rendering it an unapproved and misbranded drug in violation of the FDC Act. Furthermore, you expressed concern that Zylast Antiseptic Products have now added Ebola claims to its promotional materials.

Thank you for bringing this matter to our attention. The information that you provided will be given due consideration as this agency undertakes its regulatory activities based on Agency priorities and available resources. However, as a policy matter, we do not discuss pending or potential enforcement actions except with the firms and individuals who are the subject of those actions. Please be aware that any observations and comment about other firms' activities will be directed only to those parties.

Sincerely,

Sudha Shukla
Project Management Officer
CDER/Office of Unapproved New Drugs and Labeling Compliance
Food and Drug Administration
10903 New Hampshire Ave
WO51-5198
Silver Spring, MD 20993-0002
Email: Sudha.Shukla@fda.hhs.gov

From: Paul M. Hyman [<mailto:PHyman@hpm.com>]

Sent: Tuesday, December 23, 2014 11:37 AM

To: Schnedar, Cynthia

Subject: Ebola Claims for an OTC Drug

Dear Ms. Schnedar:

Attached is a letter describing violative labeling and promotional claims for an OTC topical antimicrobial drug product relating to prevention of Ebola. The manufacturer further cites the use in Ebola as evidence of the drug's effectiveness for other viruses and uses not permitted by the pending Healthcare Antiseptic Tentative Final Monograph. FDA needs to take prompt, effective action against that misbranded and unapproved new drug in order to protect the public health.

Sincerely,

Paul M. Hyman
Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005
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(202) 737-4281, direct dial

(202) 737-9329, fax
phyman@hpm.com
www.hpm.com

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privileged or confidential. If you are not the intended recipient, please
delete the e-mail and any attachments and notify us immediately.

EXHIBIT 19

LAW OFFICES
HYMAN, PHELPS & McNAMARA, P.C.

PAUL M. HYMAN

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D.C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
www.hpm.com

Direct Dial (202) 737-4281
PHyman@hpm.com

April 1, 2015

BY E-MAIL

Sudha Shukla, PharmD
Project Management Officer
Center for Drug Evaluation and Research
Office of Unapproved Drugs and Labeling Compliance
Food and Drug Administration
10903 New Hampshire Avenue, WO51-5180
Silver Spring, Maryland 20993-0002
E-mail: Sudha.Shukla@fda.hhs.gov

Dear Dr. Shukla:

I have previously called your attention to a number of clear violations of the law and FDA's regulations and policies in the labeling and promotion of the OTC antimicrobial drug Zylast by Innovative Biodefense Inc. and its marketing partner, Aquarius GEP. Now my client has discovered an action by those companies which should be particularly troubling to the Food and Drug Administration (FDA). Indeed, it may be a matter more appropriate for the Office of Criminal Investigation to pursue than the CDER Office of Compliance.

Specifically, I attach a document that was disseminated by Innovative Biodefense to a prospective customer which purports to be a statement by the FDA asserting that "All of the Zylast products are sold in compliance with the Tentative Final Monograph" I have also attached copies of emails relating to the delivery of the document to the prospective customer, which clearly show that the document was provided to the customer as "FDA information as requested," confirming the product's compliance with FDA's requirements.

The document bears the logo and name of the Food and Drug Administration. But on reading the text, it is (to put it mildly) highly unlikely that the unsigned and undated document was actually written by anyone at your agency. In addition to a number of erroneous statements regarding the Tentative Final Monograph (TFM) on Healthcare Antiseptic Drug Products, the tone, substance and implied endorsement of the Zylast

Sudha Shukla, PharmD
April 1, 2015
Page 2

HYMAN, PHELPS & McNAMARA, P.C.

products do not resemble a typical written statement by the agency relating to the status of OTC drug products (or any other subject, for that matter).

Here are some examples of the incorrect and questionable statements in the document.

- In addition to the startling confirmation of the compliance of “all of the Zylast products” with the TFM, the first sentence of the second paragraph continues: “as are all antimicrobial products on the market today.” I find it very hard to believe that FDA would agree that all of these antimicrobial products comply with the TFM.
- The same paragraph states that certain Zylast products “contain BZT (0.2%) in the allowed concentrations” and, along with alcohol, “are within the range specified by the FDA.” In fact, BZT is classified as a Category III ingredient in the TFM preamble, 59 Fed. Reg. 31402, 31435 (June 17, 1994). Moreover, FDA does not “allow” or “specify” ingredients under the ongoing review. The agency would not use such terms to apply to OTC drugs marketed prior to the establishment of a final OTC monograph. See, e.g., Compliance Policy Guides sections 450.200 and 450.300.
- The third paragraph asserts that FDA does not allow claims against specific pathogens, which is essentially correct but is not spelled out in the TFM. (This seems to contradict the earlier assurance that the Zylast products comply with the TFM, in light of the blatant use of such unpermitted claims on the Innovative Biodefense website.)
- The statement that “[t]he FDA does allow three claims” and the description of those claims completely misinterpret the TFM. The references to “rapid kill,” “broad spectrum” and “persistent” are all included in the definitions section of the TFM, § 333.403, and not in the labeling provisions, § 333.450. Your agency would be highly unlikely to refer to those definitions as “allowable claims.”
- The reference to the “allowed claim” for “persistent” use includes the statement: “We [sic] believe that Zylast is the only hand sanitizer product currently on the market able to make this claim, though several surgical scrubs do.” This implicit endorsement is an extreme departure from FDA’s

Sudha Shukla, PharmD
April 1, 2015
Page 3

HYMAN, PHELPS & MCNAMARA, P.C.

usually careful and objective discussion of drugs subject to the OTC review.

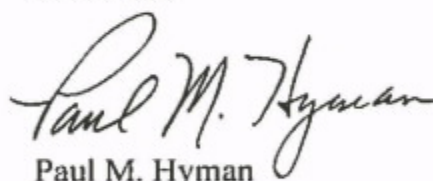
- The discussion in the last paragraph of the requirements and limitations on OTC drugs with approved New Drug Applications displays an unusually negative view of the NDA process for the agency. I cannot recall ever seeing a statement by FDA that denigrates the NDA in this manner.

In sum, the document reads very much like a promotional piece for the Zylast products. It is hard to believe that anyone at FDA would disseminate such a document.

Instead, this appears to be a new and intentionally deceptive way for Innovative Biodefense and its marketing partner, Aquarius, to induce prospective customers to believe FDA endorses the Zylast products. In doing so, they are going beyond their already well documented promotion of the products for uses that contravene the law and FDA policies. The apparently deliberate false and fraudulent use of the agency's name seems to be a matter that requires the attention of the OCI or the Office of Chief Counsel. I would be willing to present this matter to those offices if you believe it would be appropriate.

Thank you for your swift attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul M. Hyman". The signature is fluid and cursive, with the first name "Paul" being the most prominent.

Paul M. Hyman

PMH/cam
Attachments

ATTACHMENT 1



U.S. Department of Health and Human Services

Food and Drug Administration

FDA Approval Process for Antimicrobial Products

The FDA does not formally “approve” individual hand hygiene products. Like with many products, the FDA regulates the industry using a Tentative Final Monograph (TFM), which was published in 1994. In this document, the FDA lays out approved active ingredients (alcohol, BZT, iodine) and their approved concentrations. All sanitizers currently on the market fall under this TFM.

All of the Zylast products are sold in compliance with that Tentative Final Monograph, as are all antimicrobial products on the market today. The Zylast Antiseptic Lotion and Foaming Soap contain BZT (0.2%) in the allowed concentrations as the active ingredient, while the Antiseptic and Surgical Scrub have ethanol (76%) as the active ingredient. Both of these are within the range specified by the FDA.

In the same document, the FDA strictly regulates and defines the claims that an antimicrobial product can make. No product is allowed to claim efficacy against a specific pathogen (MRSA, VRE, etc.), viruses, or the ability to reduce illness.

The FDA does allow three claims to be made under the tentative final monograph.

Rapid kill: This claim is reserved for those products which kill at a 99.99% level within 15 seconds.

Broad spectrum: This claim means that the product kills 25 different gram negative and gram positive strains of bacteria as specified by the FDA.

Persistent: This claim means that six hours after the product is applied to the hand, it shows less bacteria than before application. We believe that Zylast is the only hand sanitizer product currently on the market able to make this claim, though several surgical scrubs do.

Some products, most notably those containing CHG (Chlorhexadine Gluconate), were not included in that 1994 Tentative Final Monograph. Products with these active ingredients had to go through the entire FDA New Drug Application process in order to demonstrate that they were just as safe and effective as the active ingredients listed in the TFM. Among the products to go through this process were Hibiclens and Avagard. They received no additional benefit or claims from the FDA during their regulatory process, and are only able to make the same claims as the active ingredients that were originally placed on the TFM.

ATTACHMENT 2

From: Dan Putalik [<mailto:putalik@aquariusgep.com>]
Sent: Friday, March 20, 2015 12:06 PM
To: Jason Tillis
Cc: Francisco Gomez; malovany@aquariusgep.com
Subject: RE: Request to confirm meeting time Monday - Aquarius GEP

Hi Jason,

2 pm is perfect. Looking forward to meeting with you.

I have attached the FDA information as requested. We are the only hand sanitizing company to date that has the ability to make the claim of 6 hour persistence on the outside of the bottle!

Additionally, I will bring samples, sell sheets and additional relevant information for you and your team. The price excel doc' is useful for comparison and we look forward to discussing with you.

Thank you for your time and consideration.

All the best, Dan

From: Jason Tillis [<mailto:jtillis@imperialbag.com>]
Sent: Friday, March 20, 2015 11:46 AM
To: Dan Putalik
Cc: Francisco Gomez
Subject: RE: Request to confirm meeting time Monday - Aquarius GEP

Dan

Can you provide documentation that all your product claims are FDA complaint? If not, I'd like to postpone the meeting until this can be provided.

From: Jason Tillis
Sent: Friday, March 20, 2015 11:11 AM
To: 'Dan Putalik'
Cc: Francisco Gomez
Subject: RE: Request to confirm meeting time Monday - Aquarius GEP

How's 2pm?

Use 394 Duncan ave for navigation

From: Dan Putalik [<mailto:putalik@aquariusgep.com>]
Sent: Friday, March 20, 2015 10:54 AM
To: Jason Tillis
Subject: Request to confirm meeting time Monday - Aquarius GEP

{00079284}

Hi Jason,

Thank you for the opportunity to meet with Ellis and myself this coming Monday, March 23rd.

Please advise a good time for you to meet with us at your office. (255 Route 1&9, Jersey City, NJ 07306)

Would late morning work?

All the best, Dan

Dan Putalik
Innovative BioDefense, Inc.
& Aquarius GEP
117 East 71st. Street
New York, NY 10021

t. 917-816-0810
f. 212-288-0137
s. redseal18
e. putalik@aquariusgep.com

{00079284}

EXHIBIT 20

From : Shah, Anuj [Anuj.Shah@fda.hhs.gov]
Sent : 4/2/2015 9:57:52 AM
To : Harley, Heath [Heath.Harley@fda.hhs.gov]; Smith, Tina (Walther) [Tina.Walther@fda.hhs.gov]
Subject : FW: New Development
Attachments : Hyman to Shukla 1 April 2015 re Zylast (00080099).pdf

In case I didn't already forward this

From: Miller, Elizabeth
Sent: Wednesday, April 01, 2015 5:49 PM
To: Shah, Anuj
Subject: FW: New Development

From: Schnedar, Cynthia
Sent: Wednesday, April 01, 2015 5:28 PM
To: phyman@hpm.com
Cc: Miller, Elizabeth
Subject: FW: New Development

Thank you for your communication. I am forwarding it to the attention of Elizabeth Miller in our Office of Unapproved Drugs and Labeling Compliance.

From: Paul M. Hyman [mailto:PHyman@hpm.com]
Sent: Wednesday, April 01, 2015 4:50 PM
To: Schnedar, Cynthia
Subject: FW: New Development

Dear Ms. Schnedar:

I received an out-of-office message from Dr. Shukla in response to my email below. She will not return until April 12.

However, I believe that the subject of my email -- the misuse of the FDA's name (with inaccurate information) to promote an OTC drug - should be of immediate concern to your office, or perhaps to OCI or OCC.

I would appreciate the opportunity to discuss this matter with you or one of your colleagues tomorrow.

Sincerely,

Paul M. Hyman

Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-4281, direct dial
(202) 737-9329, fax
phyman@hpm.com
www.hpm.com
Visit the HPM blog at: www.fdalawblog.net

From: Paul M. Hyman
Sent: Wednesday, April 01, 2015 4:01 PM
To: Sudha Shukla (Sudha.Shukla@fda.hhs.gov)
Subject: New Development

Dear Dr. Shukla:

Attached is a document which adds a surprising new, and troubling, wrinkle to the noncompliant promotion of Zylast by Innovative Biodefense and Aquarius. It now appears that those companies are claiming that FDA confirms that Zylast complies with the applicable TFM and, in effect, that the agency implicitly endorses the product. This deceptive practice should be of particular concern to your agency.

I would like to discuss this new information with you as soon as you have had an opportunity to review it. To that end, I will call your office tomorrow morning to follow up on this email.

Sincerely,

Paul M. Hyman

Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-4281, direct dial
(202) 737-9329, fax
phyman@hpm.com

www.hpm.com
Visit the HPM blog at: www.fdalawblog.net

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privileged or confidential. If you are not the intended recipient, please
delete the e-mail and any attachments and notify us immediately.

EXHIBIT 21

Message

From: Miller, Elizabeth [Elizabeth.Miller@fda.hhs.gov]
Sent: 4/10/2015 8:33:57 PM
To: Shah, Anuj [Anuj.Shah@fda.hhs.gov]; Smith, Tina (Walther) [Tina.Walther@fda.hhs.gov]; Harley, Heath [Heath.Harley@fda.hhs.gov]
Subject: FW: Continuing violations
Attachments: FDA Approval Process for Antimicrobial Products.pdf; Zylast in Hotels.pdf; Message from Unknown sender (2027374281)

Attached vm too

From: Paul M. Hyman [mailto:PHYman@hpm.com]
Sent: Friday, April 10, 2015 2:25 PM
To: Miller, Elizabeth
Subject: Continuing violations

Dear Ms. Miller:

As I stated in my voicemail today, Innovative BioDefense, Inc. and Aquarius GEP are continuing to use the document identified with the Food and Drug Administration letterhead to promote their Zylast products. My client has received another copy of the identical document, which I have attached, from a potential customer (who wishes to remain unidentified at this time). Thus it is clear that those companies' ongoing promotional activities include the false representation that FDA has concluded the "[a]ll of the Zylast products are sold in compliance with that Tentative Final Monograph." That alone should prompt the agency to take immediate action to halt such egregiously violative conduct.

As I also have informed your office on several occasions, those companies have consistently promoted their products for uses that make them misbranded and unapproved new drugs. In that connection, I attach another document disseminated by those companies which blatantly lays out these violative claims, "Benefits of Zylast in Hotels." This promotional piece highlights the claim "Effective against Viruses," identifying norovirus and a number of others which the products have "been shown to kill." It also makes the persistence claim and outrageous superior efficacy claims. None of these claims are supported by the TFM, and they expose the public to unapproved products for potentially serious conditions.

It is clear that unless FDA takes prompt and vigorous action to halt these violative activities, the public, competitors and the agency itself will continue to be deceived and harmed.

Sincerely,
Paul M. Hyman

Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005
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(202) 737-4281, direct dial
(202) 737-9329, fax
phyman@hpm.com
www.hpm.com
Visit the HPM blog at: www.fdalawblog.net

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FDA Approval Process for Antimicrobial Products

The FDA does not formally “approve” individual hand hygiene products. Like with many products, the FDA regulates the industry using a Tentative Final Monograph (TFM), which was published in 1994. In this document, the FDA lays out approved active ingredients (alcohol, BZT, iodine) and their approved concentrations. All sanitizers currently on the market fall under this TFM.

All of the Zylast products are sold in compliance with that Tentative Final Monograph, as are all antimicrobial products on the market today. The Zylast Antiseptic Lotion and Foaming Soap contain BZT (0.2%) in the allowed concentrations as the active ingredient, while the Antiseptic and Surgical Scrub have ethanol (76%) as the active ingredient. Both of these are within the range specified by the FDA.

In the same document, the FDA strictly regulates and defines the claims that an antimicrobial product can make. No product is allowed to claim efficacy against a specific pathogen (MRSA, VRE, etc.), viruses, or the ability to reduce illness.

The FDA does allow three claims to be made under the tentative final monograph.

Rapid kill: This claim is reserved for those products which kill at a 99.99% level within 15 seconds.

Broad spectrum: This claim means that the product kills 25 different gram negative and gram positive strains of bacteria as specified by the FDA.

Persistent: This claim means that six hours after the product is applied to the hand, it shows less bacteria than before application. We believe that Zylast is the only hand sanitizer product currently on the market able to make this claim, though several surgical scrubs do.

Some products, most notably those containing CHG (Chlorhexadine Gluconate), were not included in that 1994 Tentative Final Monograph. Products with these active ingredients had to go through the entire FDA New Drug Application process in order to demonstrate that they were just as safe and effective as the active ingredients listed in the TFM. Among the products to go through this process were Hibiclens and Avagard. They received no additional benefit or claims from the FDA during their regulatory process, and are only able to make the same claims as the active ingredients that were originally placed on the TFM.

Benefits of Zylast in Hotels

The purpose of hand hygiene in hotels is simple – to reduce illness among guests and employees. Zylast is a full line of antimicrobial products, offering unique benefits to hotels.

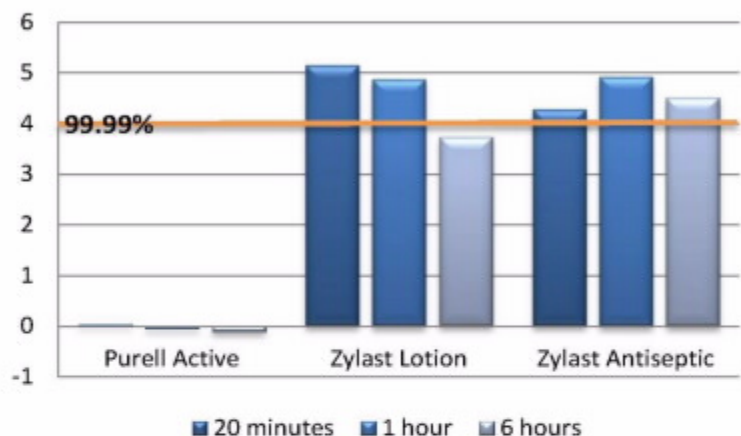


1. Persistence for Six Hours

Traditional soaps and sanitizers only work when they are on the hands – about 15 seconds – and then are gone. After they have been applied, the hands can immediately become recontaminated by the next surface touched.

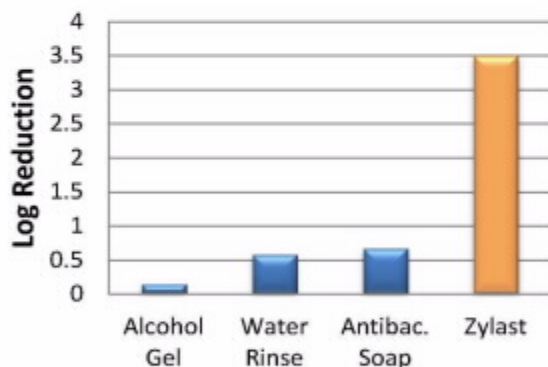
Zylast is different, offering six hour persistence with all products, so that the hands continue to be protected after application.

Persistent Efficacy on Human Skin



2. Effective against Viruses

Norovirus Reduction



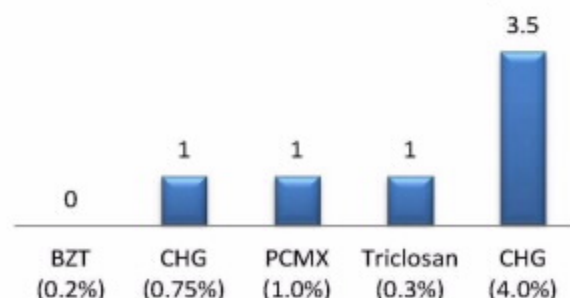
Traditional soaps and sanitizers have relatively little effect against many viruses. Against the Norovirus, the cause of the stomach flu, alcohol sanitizers were shown to be less effective than just rinsing the hands with water. Zylast was shown to be more than 100 times more effective than antibacterial soap, plain water rinse, or alcohol sanitizers.

Zylast has also been shown to kill more than 99% of HIV, influenza, H₁N₁, Rotavirus, Rhinovirus, Herpes, and others on contact.

3. Reducing Skin Irritation

Alcohol sanitizers work by dehydrating and killing the bacteria – unfortunately they do the same to the skin. Zylast feels like a high-end lotion, moisturizes the skin, and has no irritation, even when used 100 times daily for 5 straight days. Zylast is not flammable or combustible, all-natural, hypoallergenic, and non-toxic.

Skin Irritation after 5 Days



4. Fast-Acting

Most soaps currently on the market take at least 2 minutes to be completely effective against germs. However, studies show that when people wash their hands, the average time they spend is about 11 seconds. Something faster-acting is needed, and Zylast was designed to destroy germs in 15 seconds.



	HibiClens (4% CHG)*	Zylast Antiseptic (76% ethanol)**	Zylast Lotion (0.2% BZT)**
<i>Acinetobacter baumannii</i>	1 min	15 seconds	15 seconds
<i>Bacteroides fragilis</i>	10 minutes	15 seconds	30 seconds
<i>Enterococcus faecalis</i>	10 minutes	15 seconds	15 seconds
<i>Enterococcus faecium</i>	10 minutes	15 seconds	15 seconds
<i>Staphylococcus aureus</i>	10 minutes	15 seconds	30 seconds
<i>Staphylococcus epidermis</i>	3 min	15 seconds	15 seconds
<i>S. saprophyticus</i>	3 min	15 seconds	15 seconds
<i>Streptococcus pyogenes</i>	10 minutes	15 seconds	15 seconds

Zylast in Action

All of these benefits have been shown to be vital in real-world situations. When used in the workplace, Zylast decreases illness among employees by 24.3% - an average of 2 extra healthy days each year. In schools, Zylast reduced illness outbreaks by 87.5%, and overall illness absenteeism by nearly 40%. When used in hospitals, Zylast reduced Hospital-Acquired Infections by 23.1%, where alcohol sanitizers had shown no benefit.

Zylast products are all-natural, made in the United States, fully compliant with FDA regulations, and have an unmatched safety profile.

Pricing

We believe that all hotels should have access to this technology. Zylast will match, shot-for-shot, the price that you are currently getting for your hand sanitizer products. Because Zylast uses so much less product per shot – 0.4 ml vs. 2.0 ml of alcohol sanitizers – we nearly always save a hotel between 10 and 25% over their current products. In addition, the ability to reduce illness days among employees, keep guests safe and healthy, and increased satisfaction with hand hygiene products has the ability to save a hotel thousands of dollars each year.



Zylast – A Revolution in Hand Hygiene



Message

From: Cisco Unity Connection Messaging System [unityconnection@fdsla04029.fda.hhs.gov]
Sent: 4/10/2015 5:45:14 PM
To: millere@fdsla04029.fda.hhs.gov
Subject: Message from Unknown sender (2027374281)
Attachments: VoiceMessage.wav

EXHIBIT 23

To: Harley, Heath[Heath.Harley@fda.hhs.gov]; Smith, Tina (Walther)[Tina.Walther@fda.hhs.gov]; Shah, Anuj[Anuj.Shah@fda.hhs.gov]
Cc: Miller, Elizabeth[Elizabeth.Miller@fda.hhs.gov]
From: Shukla, Sudha
Sent: Wed 4/15/2015 9:24:05 PM (UTC)
Subject: FW: Message from Unknown sender (2027374281)
Last Modified: Wed 2/21/2018 7:11:24 AM (UTC)
[VoiceMessage.wav](#)

Hi All,

I received the below message from Mr. Paul Hyman regarding Zylast. Please let me know how you would like me to handle this.

Thanks,
Sudha

From: Cisco Unity Connection Messaging System [mailto:unityconnection@fdsla04029.fda.hhs.gov]
Sent: Wednesday, April 15, 2015 4:51 PM
To: shuklasu@fdsla04029.fda.hhs.gov
Subject: Message from Unknown sender (2027374281)

EXHIBIT 25

EXHIBIT
Smith 7
5.30.19 bc

EXHIBIT 26

Message

From: Paul M. Hyman [PHyman@hpm.com]
Sent: 5/13/2015 6:04:50 PM
To: Shukla, Sudha [Sudha.Shukla@fda.hhs.gov]
Subject: Continuing violative marketing
Attachments: Hyman to Shukla 13 May 2015 re Qore-24, Germ Free 24 and SkinGuard14 (00096203).pdf

Dear Dr. Shukla:

Attached is a letter which describes the continuing violative labeling and promotion of OTC health care and consumer antiseptics for use to prevent viruses, MRSA and other diseases and conditions for which they are unapproved new drugs. The companies identified include Innovative Biodefense Inc., [CCI] [CCI] who were the subjects of my previous correspondence to your office. They are joined here by another company, [CCI] with virtually identical claims to those made by the other companies for their products.

There are many other companies marketing products with similar violative claims. Swift and decisive action by FDA against these identified entities could help to stop that conduct and protect the public health.

Sincerely,

Paul M. Hyman
 Hyman, Phelps & McNamara, P.C.
 700 13th Street, NW, Suite 1200
 Washington, DC 20005
 (202) 737-5600
 (202) 737-4281, direct dial
 (202) 737-9329, fax
phyman@hpm.com
www.hpm.com

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EXHIBIT 27

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

PAUL M. HYMAN

700 THIRTEENTH STREET, N.W.

SUITE 1200

WASHINGTON, D.C. 20005-5929

(202) 737-5600

FACSIMILE

(202) 737-9329

www.hpm.com

Direct Dial (202) 737-4281
Phyman@hpm.com

May 13, 2015

BY E-MAIL

Sudha Shukla, PharmD
Project Management Officer
Center for Drug Evaluation and Research
Office of Unapproved Drugs and Labeling Compliance
Food and Drug Administration
10903 New Hampshire Avenue, WO51-5180
Silver Spring, Maryland 20993-0002
E-mail: Sudha.Shukla@fda.hhs.gov

Dear Dr. Shukla:

As you know, I recently called your office's attention to more extensive violations by Innovative Biodefense Inc. with respect to labeling and promotion of its topical antibacterial drug, Zylast, than those I had noted in an earlier letter dated November 7, 2013, to Howard Sklamberg, then-director of the CDER Office of Compliance. I would hope that, by now, you have enough information to take vigorous regulatory action against this misbranded and unapproved new drug.

My November 7, 2013 letter also cited violative claims for [CCI]

CCI

CCI

Both of those products continue to be promoted with the same blatantly violative claims identified in my November 7, 2013 letter. Furthermore, their market penetration has increased significantly since then.

CCI

CCI

It also still claims that [CCI]

CCI

Sudha Shukla, PharmD
May 13, 2015
Page 2

HYMAN, PHELPS & MCNAMARA, P.C.

CCI

CCI

The marketers of these products, like Zylast's manufacturer and distributor, and numerous others, clearly feel no pressure to comply with the pending TFM for OTC health care antiseptic drug products or the agency's express policies on such products. The absence of FDA regulatory action in this area, unfortunately, supports such an attitude. As a result, consumers and health care personnel are put at risk from viruses and MRSA to the extent they rely on these unproven and unapproved products. Competitors who do comply with the law and FDA's policies are placed at a great disadvantage in the marketplace when faced with the grand, but unlawful, promises made for these products.

It is clear that there are growing numbers of companies making these claims. FDA needs to move against them swiftly to halt this unlawful conduct and to protect the public health.

Sincerely,


Paul M. Hyman

PMH/cam

EXHIBIT 28

Message

From: Shukla, Sudha [/O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SHUKLASU]
Sent: 8/10/2015 12:44:32 AM
To: Harley, Heath [Heath.Harley@fda.hhs.gov]; Smith, Tina (Walther) [Tina.Walther@fda.hhs.gov]; Shah, Anuj [Anuj.Shah@fda.hhs.gov]
Subject: FW: Zylast promotion
Attachments: Zylast Benefits in Hospitals (00135809).pdf; ZylastXP Six Hours (00135807).pdf

Hi All,

Please see the below email from Mr. Hyman regarding Zylast.

Sudha

From: Paul M. Hyman [mailto:PHyman@hpm.com]
Sent: Wednesday, August 05, 2015 5:15 PM
To: Shukla, Sudha
Subject: Zylast promotion

Dear Ms. Shukla:

As you can understand, I was gratified to see that FDA issued a warning letter on June 30, 2015 challenging Innovative Biodefense Inc.'s (IBD's) consistently violative promotion of its Zylast antiseptic product line. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm453717.htm> The letter reflected a number of concerns that I had raised in communications with you.

However, I was disturbed to learn that, on July 16, 2015, more than 2 weeks after the warning letter issued, Germ Logic, a Zylast distributor, made a presentation to the San Antonio APIC chapter which blatantly ignored the agency's concerns in the warning letter. The presentation focused on the Zylast products and included distribution of the attached sell sheets. As you will see, those sell sheets reiterate almost all of the claims cited in the warning letter, with particular emphasis on antiviral, MRSA and persistence claims. One of the documents again states that the "Zylast products are ... fully compliant with FDA regulations"

Thus, it appears that the Zylast products are still being promoted with claims that violate the law and FDA's policies that were explicitly delineated and applied to those products in the warning letter. While these promotional activities were apparently conducted by a distributor, it seems highly unlikely that the distributors were not made aware of the warning letter, even if IBD may not have been directly involved in the program. I am sure that FDA would not tolerate the situation where distributors are allowed to continue to promote a misbranded and unapproved new drug despite the agency's regulatory action against the manufacturer of that drug.

In that connection, I was astounded to discover that, even today, IBD itself is continuing to make antiviral, MRSA, Ebola and persistence claims on its websites. <http://www.zylast.com/>, <http://www.zylastdirect.com/>. Apparently, the company believes that it has "corrected" the violations cited in the warning letter by adding the following statements at the bottom of each page:

"The information on this website is for educational purposes only. Zylast does not make, and the FDA does not allow from any manufacturer, claims of efficacy against specific bacteria or viruses."

"This information is for educational purposes only. Zylast does not make, and the FDA does not approve, claims of effectiveness against specific bacteria or viruses."

I cannot believe FDA would accept this laughable response as addressing the agency's concerns in the warning letter. In essence, IBD is asserting the right to make outrageously violative claims as long as they are accompanied by a disclaimer

to the effect that they are “educational” and not allowed by FDA. Imagine how this policy would be welcomed by many in the regulated community.

In summary, it does not appear that IBD is really complying with the law and FDA’s policies. Instead, the company and its agents are continuing to disseminate violative information and claims for the Zylast products. FDA should take prompt and decisive action to halt that activity.

Sincerely,

Paul M. Hyman
Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, DC 20005
(202) 737-5600
(202) 737-4281, direct dial
(202) 737-9329, fax
phyman@hpm.com
www.hpm.com

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EXHIBIT 29

Message

From: Smith, Tina (Walther) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=WALTHER]
on behalf of Smith, Tina (Walther) [/O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=WALTHER]
Sent: 8/10/2015 3:16:55 PM
To: Miller, Elizabeth [Elizabeth.Miller@fda.hhs.gov]
CC: Harley, Heath [Heath.Harley@fda.hhs.gov]; Shukla, Sudha (Sudha.Shukla@fda.hhs.gov)
[Sudha.Shukla@FDA.HHS.GOV]
Subject: FW: Zylast promotion

Forwarding to Elizabeth to loop her in. Once we sent our response to Zylast and Elizabeth comes back from leave, lets regroup about how we want to proceed with this case.

Tina

-----Original Message-----

From: Shukla, Sudha
Sent: Sunday, August 09, 2015 8:51 PM
To: Harley, Heath; Smith, Tina (Walther); Shah, Anuj
Subject: FW: Zylast promotion

FYI

-----Original Message-----

From: Schnedar, Cynthia
Sent: Thursday, August 06, 2015 10:58 AM
To: Miller, Elizabeth
Cc: Shukla, Sudha
Subject: FW: Zylast promotion

-----Original Message-----

From: Schnedar, Cynthia
Sent: Thursday, August 06, 2015 10:58 AM
To: 'Paul M. Hyman'
Cc: Shukla, Sudha
Subject: RE: Zylast promotion

I want to acknowledge receipt of your email. We will review the information you have provided.

-----Original Message-----

From: Paul M. Hyman [mailto:PHYman@hpm.com]
Sent: Thursday, August 06, 2015 10:49 AM
To: Schnedar, Cynthia
Subject: FW: Zylast promotion

Dear Ms. Schnedar:

Last evening I sent the email below to Sudha Shukla, describing the current response of Innovative Biodefense Inc. (IBD) to the warning letter you and Mary Engle of the FTC jointly sent to IBD objecting to the company's violative promotion of its Zylast products.

Having received an out-of-office message from Ms. Shukla, I am forwarding my communication to you for your information. As you will see, IBD has apparently decided it can comply with the law and regulations simply by continuing to make the violative claims and adding a disclaimer that the claims "are for educational purposes only." While that "innovative ..defense" would undoubtedly appeal to many other targets of agency regulatory action, I seriously doubt that FDA (or the FTC) would find it an acceptable response to the warning letter.

Moreover, as shown by the attachments, distributors of IBD's Zylast products are still promoting them with claims that render the products misbranded and unapproved new drugs.

These actions would seem to warrant further attention by FDA.

Sincerely,

Paul M. Hyman
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From: Paul M. Hyman
Sent: Wednesday, August 05, 2015 5:15 PM
To: Sudha Shukla (Sudha.Shukla@fda.hhs.gov)
Subject: Zylast promotion

Dear Ms. Shukla:

As you can understand, I was gratified to see that FDA issued a warning letter on June 30, 2015 challenging Innovative Biodefense Inc.'s (IBD's) consistently violative promotion of its Zylast antiseptic product line. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm453717.htm> <<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm453717.htm>> The letter reflected a number of concerns that I had raised in communications with you.

However, I was disturbed to learn that, on July 16, 2015, more than 2 weeks after the warning letter issued, Germ Logic, a Zylast distributor, made a presentation to the San Antonio APIC chapter which blatantly ignored the agency's concerns in the warning letter. The presentation focused on the Zylast products and included distribution of the attached sell sheets. As you will see, those sell sheets reiterate almost all of the claims cited in the warning letter, with particular emphasis on antiviral, MRSA and persistence claims. One of the documents again states that the "Zylast products are ... fully compliant with FDA regulations ..."

Thus, it appears that the Zylast products are still being promoted with claims that violate the law and FDA's policies that were explicitly delineated and applied to those products in the warning letter. While these promotional activities were apparently conducted by a distributor, it seems highly unlikely that the distributors were not made aware of the warning letter, even if IBD may not have been directly involved in the program. I am sure that FDA would not tolerate the situation where distributors are allowed to continue to promote a misbranded and unapproved new drug despite the agency's regulatory action against the manufacturer of that drug.

In that connection, I was astounded to discover that, even today, IBD itself is continuing to make antiviral, MRSA, Ebola and persistence claims on its websites. <http://www.zylast.com/>, <http://www.zylastdirect.com/> <<http://www.zylastdirect.com/>> . Apparently, the company believes that it has "corrected" the violations cited in the warning letter by adding the following statements at the bottom of each page:

"The information on this website is for educational purposes only. Zylast does not make, and the FDA does not allow from any manufacturer, claims of efficacy against specific bacteria or viruses."

"This information is for educational purposes only. Zylast does not make, and the FDA does not approve, claims of effectiveness against specific bacteria or viruses."

I cannot believe FDA would accept this laughable response as addressing the agency's concerns in the warning letter. In essence, IBD is asserting the right to make outrageously violative claims as long as they are accompanied by a disclaimer to the effect that they are "educational" and not allowed by FDA. Imagine how this policy would be welcomed by many in the regulated community.

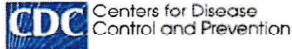
In summary, it does not appear that IBD is really complying with the law and FDA's policies. Instead, the company and its agents are continuing to disseminate violative information and claims for the Zylast products. FDA should take prompt and decisive action to halt that activity.

Sincerely,

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privileged or confidential. If you are not the intended recipient, please
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EXHIBIT 30



Ebola (Ebola Virus Disease)

Hand Hygiene in Non-U.S. General Healthcare Settings

Ebola is transmitted when a noninfected person comes into direct contact with the blood or body fluids of an infected person. The virus in blood and body fluids can enter the body through broken skin or mucous membranes in the eyes, nose, or mouth. **In most cases, it is thought that exposure happens by touching the face with contaminated hands.**

Hand hygiene is a primary component of Standard Precautions that provides a basic level of patient safety and protection for healthcare personnel, and is an effective strategy in preventing the spread of dangerous germs like Ebola in the general healthcare setting.

In healthcare settings where Ebola is present, hand hygiene should be performed¹

- Before putting on gloves and wearing personal protective equipment (PPE) on entry to the isolation room/area.
- Before any clean or sterile procedures are performed on a patient.
- After any exposure risk or actual exposure with the patient's blood and body fluids.
- After touching (even potentially) contaminated surfaces/items/equipment in the patient's surroundings.
- After removal of PPE, upon leaving the care area.

Hand hygiene may be performed with soap and water, alcohol-based hand sanitizer, or, in settings where neither is locally available, a mild (0.05%) chlorine solution. Recommendations and considerations for each method are described below.

Alcohol-based Hand Sanitizer

Alcohol-based hand sanitizer is the preferred method of routine hand hygiene in healthcare settings **when hands are not visibly soiled.**^{2, 3} This is because of its ability to kill germs like Ebola. It is quick to apply to

hands and to air dry, and it is gentler to the skin during frequent use than even soap and water. *CDC defines alcohol-based hand sanitizer as an alcohol-containing preparation designed for application to the hands for reducing the number of viable microorganisms on the hands.*³ Such solutions usually contain 60% to 95% ethanol or isopropanol, and they can be produced locally using ingredients available even in lower-resourced settings.⁴ Alcohol-based hand sanitizer **should not be used** when hands are visibly soiled with dirt, blood, or other body fluids.

Hands are the main way germs like Ebola are transmitted during health care, either between patients or from the patient to the healthcare personnel. Correct hand hygiene reduces the number of germs on the hands and limits the opportunity for spread.

Soap and Water

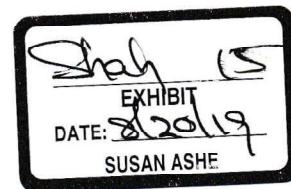
Use soap and water when hands are visibly soiled with dirt, blood, or other body fluids and as an alternative to alcohol-based hand sanitizer. Although antimicrobial soaps are often used in some healthcare settings, it has not been proven to offer benefit over washing hands with plain soap (non-antimicrobial) and water.

Mild Chlorine Solution

In settings where neither alcohol-based hand rub nor soap and water are available, mild chlorine solution (0.05%) may be considered for hand hygiene. Repeated use of 0.05% chlorine solution for hand hygiene may cause skin irritation.

References





1. Infection Prevention and Control (IPC) Guidance Summary: Ebola Guidance Package . World Health Organization.



8/19/2019 Hand Hygiene in Non-U.S. General Healthcare Settings | Non-U.S. General Healthcare Settings | Clinicians | Ebola (Ebola Virus Disease...

2. Guidelines for Hand Hygiene in Healthcare Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force  [PDF – 56 pages].
3. Guidelines on Hand Hygiene in Health Care  . World Health Organization.
4. Alcohol-based Handrub Formulation and Production  . World Health Organization.

Hand Hygiene Resources

- CDC Hand Hygiene Website
- HICPAC: Guidelines for Hand Hygiene in Healthcare Settings  [PDF – 56 pages]
- WHO | Five Moments for Hand Hygiene 
- Hand Washing for African Health Workers (English)  [PDF – 1 page]
- Hand Washing for African Health Workers (French)  [PDF – 1 page]

Page last reviewed: May 3, 2019